UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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FEDERAL TRADE COMMISSION, STATE OF NEW YORK, STATE OF CALIFORNIA, STATE OF OHIO, COMMONWEALTH OF PENNSYLVANIA, STATE OF ILLINOIS, STATE OF NORTH CAROLINA, and COMMONWEALTH OF VIRGINIA,

Plaintiffs,

v. 20 CV 706 (DLC)

MARTIN SHKRELI, et al.,

Defendants.

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New York, N.Y.
December 17, 2021
9:30 a.m.

Before: HON. DENISE COTE,
District Judge

APPEARANCES

FEDERAL TRADE COMMISSION
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J. MANLY PARKS

(In open court)

THE COURT: Good morning, everyone.

COUNSEL: Good morning.

THE COURT: The witness can take the stand.

THE WITNESS: Good morning, your Honor.

THE COURT: Good morning. I remind you, you're still under oath.

Mr. Meier.

MR. MEIER: Good morning, your Honor. Markus Meier, on behalf of the FTC.

We would like to move some documents and exhibits in, if that's possible?

THE COURT: Sure.

MR. MEIER: So the first one we'd like to move in is actually a cleanup from yesterday. It's the exhibits related to the testimony of Mr. Mukhopadhyay that are cited in his declaration. You'll recall he testified yesterday, your Honor.

THE COURT: You're going to have to keep your voice up.

MR. MEIER: I'm sorry. Yes, your Honor, sorry.

THE COURT: To make sure every word is heard.

MR. MEIER: Yes, your Honor.

This is Government Exhibit 9010, and it's the exhibits related to the declaration of Mr. Mukhopadhyay, who testified yesterday.

THE COURT: Any objection to the receipt of GX 9010 with the exhibits listed therein?

MR. RUDOWITZ: Good morning, your Honor. AJ Rudowitz, on behalf of Mark Shkreli.

No objection.

THE COURT: Thank you.

They are received.

(Government's Exhibit 9010 with exhibits listed therein received in evidence)

MR. MEIER: The next one, your Honor, is Government Exhibit 9003.

THE COURT: Any objection to the receipt of GX 9003, with the exhibits listed therein?

MR. POLLACK: Your Honor, Jeff Pollack.

None subject to your prior rulings. Thank you.

THE COURT: Thank you.

GX 9003, with the exhibits listed therein, are received.

(Government's Exhibit 9003 with the exhibits listed therein received in evidence)

MR. MEIER: The next one, your Honor, is Government Exhibit 9005, which is our fifth listed exhibit to be admitted.

THE COURT: Any objection to the receipt of GX 9005 and each of the exhibits listed therein?

MR. POLLACK: Jeff Pollack, your Honor.

None subject to your prior rulings. Thank you.

THE COURT: Thank you.

They are received.

(Government's Exhibits 9005 with the exhibits listed therein received in evidence)

MR. MEIER: Your Honor, the next is Government Exhibit 9009.

THE COURT: Any objection to the receipt of GX 9009 and the exhibits listed therein?

MR. POLLACK: None subject to your prior rulings, your Honor. Thank you.

THE COURT: Thank you.

They are received.

(Government's Exhibit 9009 with the exhibits listed therein received in evidence)

MR. MEIER: The next, your Honor, is Government Exhibit 9065. It's the designations for the transcript of Nancy Retzlaff, and -- let me hand it up. I apologize. Apparently, there are only two copies. Sorry.

THE COURT: Any objection to the receipt of GX 9065?

MR. POLLACK: No, your Honor.

THE COURT: Received.

(Government's Exhibit 9065 received in evidence)

MR. MEIER: The next, your Honor, is Government Exhibit 9064, and it's the designations -- revised transcript

designations of Dennis Saadeh, S-a-a-d-e-h, from a company called Harrow, H-a-r-r-o-w.

THE COURT: Any objection to the receipt of GX 9064?

MR. POLLACK: No, your Honor.

THE COURT: And this one has some notations about withdrawn passages.

MR. MEIER: That is correct, your Honor. It updates what we submitted back in October.

THE COURT: Received.

(Government's Exhibit 9064 received in evidence)

MR. MEIER: The next is Government Exhibit 9063.

THE COURT: Any objection to the receipt of GX 9063?

MR. POLLACK: No, your Honor.

THE COURT: Received.

(Government's Exhibit 9063 received in evidence)

MR. MEIER: For the purposes of the court reporter, this is the transcript of the deposition of Ann Kirby, K-i-r-b-y, from Vyera.

This one, your Honor, is Government Exhibit 5009. It's the transcript of the investigational hearing of Ann Kirby from Vyera, and, similar to yesterday, we are submitting the entire investigational hearing transcript, though we did submit to the Court, back in October, a highlighted version, but for the similar reasons we had the discussion yesterday, defendants object to the admission of just the highlighted portions. So

we're admitting the entire investigational hearing transcript. I'm not sure if defendants want to be heard on that issue again today.

THE COURT: Well, obviously, this is evidence being offered by the plaintiffs, so the plaintiffs are consenting to the offer of the entire transcript?

MR. MEIER: That's right, your Honor, just for administrative ease, but I also wanted to point out to the Court that there is a highlighted version in the October submissions.

THE COURT: Yes. Thank you.

Any objection to the receipt of GX 5009?

MR. POLLACK: Nothing beyond what we discussed yesterday, your Honor.

THE COURT: Thank you.

It is received.

(Government's Exhibit 5009 received in evidence)

MR. MEIER: And the very last one, your Honor, for today, this is Government Exhibit 5011, and it's the transcript of the investigational hearing of Akeel Mithani from Vyera. And, again, this is an investigational hearing transcript. We're submitting the entire transcript today, but we also submitted to the Court, in October, highlighted versions.

THE COURT: Any objection to receipt of GX 5011?

MR. POLLACK: Nothing beyond what we've already

discussed, your Honor, yesterday.

THE COURT: It is received.

(Government's Exhibit 5011 received in evidence)

MR. MEIER: Thank you, your Honor. Plaintiffs are prepared to proceed.

MR. PARKS: Good morning, your Honor; good morning, Mr. Conroy.

THE WITNESS: Good morning.

EDWARD VINCENT CONROY,

CROSS-EXAMINATION CONTINUED

BY MR. PARKS:

Q. Sir, I want to ask you some questions, first, this morning on reference-listed drugs used in bioequivalence testing.

First, are you familiar with the term "reference-listed drug," or RLD?

A. Yes.

Q. You are also generally familiar with the concept of the use of an RLD in bioequivalence testing, correct?

A. Yes.

Q. You don't have any experience working with procurement firms to obtain RLD for use in bioequivalence testing, do you?

A. No.

Q. You have never sought a waiver from the FDA regarding the amount of RLD needed to perform bioequivalence testing, have you?

A. No. We had testimony to that effect.
Q. You also have never worked with a client to seek a waiver from the FDA regarding the amount of RLD needed to perform bioequivalence testing, have you?
A. Not that I recall.
Q. Sir, are you a medical doctor?
A. No.
Q. Do you know the basis for the addition of toxoplasmosis as an indication for Daraprim?
A. Could you repeat that question, please?
Q. Sure.

Do you know the basis for the addition of toxoplasmosis as an indication for Daraprim?

A. I'm not familiar with the original indications. I was at Burroughs Wellcome, and I do not think that occurred during my time. Yes, I do not know.
Q. Okay.

Sir, you do not have any specific knowledge concerning medical treatments for toxoplasmosis other than Daraprim, do you?

A. I'm trying to think about that.

At Burroughs Wellcome, the early GSK, and with the launch of Retrovir, I was -- and as a medical center rep, heavily trained by the Wellcome. I had some familiarity, or was trained in some of the familiarity, with uses of that drug

and other drugs. We had a drug called Septra.

THE COURT: So, counsel, I just want to remind you that, at your choice, you may, if you wish, remove your mask while at the lectern.

MR. PARKS: Thank you. I forgot to do that.

BY MR. PARKS:

Q. Sir, just to make sure we're clear on this, you were deposed in this case on July 14, 2021, correct?

A. Yes.

Q. And do you recall you were asked a question about this issue, what knowledge you had concerning medical treatments for toxoplasmosis other than Daraprim?

A. Yes.

Q. Do you remember that your testimony, when you were asked, "Is the answer to the question that you do not have any knowledge concerning treatments for toxoplasmosis other than Daraprim," was "Not specifically, no"? Does that sound right to you?

A. Yes.

Q. And that's your testimony here today?

A. Yes.

Q. Sir, you don't have any expertise in the use of Daraprim for the treatment of toxoplasmosis, do you?

A. I haven't studied the package insert. I do know it's three times a day dosage.

Q. But you don't have any expertise in the use of Daraprim for the treatment of toxoplasmosis, do you?
A. Not directly, no.
Q. You are not familiar with Daraprim's side effects, are you?
A. Not that I could recite to you.
Q. Sir, you have no experience with the risk profile of Daraprim, do you?
A. I would say, actually, I have a reasonable amount of familiarity in the sense of, since 1975, all my days at GSK, nothing arose to my attention through these medical committees I mentioned yesterday that I worked on, joint committees. There was never any HIV drugs. It never rose to a level that I recall, and from that, I would assume there weren't any new or significant issues with Daraprim, and there would have been some FDA letters that I would think the plaintiffs might have -- that may have come to light during this testimony, because something new, then the FDA sends a letter out, and I think you're familiar with that.
Q. Sir, do you recall at your deposition, back in July, you were asked, "Do you have any" experience -- I'm sorry, "expertise in the risk profile of Daraprim?"

And your answer was, "Specifically, no"?

A. Yes.
Q. And that's your testimony here today?
A. Yes. It might have -- you know, you continue to read all

this material, and little things, after all these years, you know, slowly pop into your mind. But, in general, that is true.

Q. Sir, you are not familiar with Daraprim's side effects, are you?

A. Not directly, no.

Q. In preparing your report, you did not review adverse events that had been reported to the FDA regarding Daraprim, did you?

A. No. I reviewed all the documents, and I don't -- as I said, as a distribution expert, I'm able to read all that. I did not see anything that even suggested there was reports to the FDA and there was actions being taken either by GSK or any of the other -- that GSK had to deal with.

Q. You didn't review all the documents in this case, did you, sir?

A. The ones that are listed in the -- that were shared with me, yes.

Q. And the FDA told you or sent you those documents, didn't it?

THE COURT: FDA or FTC?

MR. PARKS: I'm sorry, the FTC. Thank you.

THE WITNESS: Yes, the source of the documents were the FTC.

BY MR. PARKS:

Q. Thank you.

In preparing your report, you did not have any information regarding the number of adverse events reported to the FDA regarding Daraprim, did you?

A. No.

Q. Now, I want to talk a little bit about the scope of your assignment here.

In this engagement, you were not asked to opine on whether any specific generic manufacturer tried to purchase Daraprim directly from Vyera, were you?

A. No.

Q. You also were not asked to offer an opinion on whether any of Vyera's distribution practices, in fact, delayed market entry by any specific generic manufacturer, were you?

A. Please repeat the question?

Q. Sure.

You were not asked to offer an opinion on whether any of Vyera's distribution practices, in fact, delayed market entry by any specific generic manufacturer, were you?

A. I was not asked to opine, but in -- if you can find it --

Q. Well, I can stop you right there. That's my question.

A. All right.

Q. You were also not asked to opine on whether data blocking, in fact, caused a delay in market entry by any specific generic manufacturer, were you?

A. Did you say "opine"? No, I was not asked to opine.

Q. Sir, you were not asked to offer any opinion regarding whether Vyera's distribution partners were motivated by any anticompetitive intent, were you?
A. No.
Q. In fact, you don't consider yourself able to gauge anyone's intent in this case, do you?
A. No.
Q. So you were not offering any opinion regarding Vyera's intent, correct?
A. No.
Q. No, it's incorrect or, no, you are not offering such an opinion?
A. I was not asked to offer such an opinion.
Q. And you are not offering one, correct?
A. No.
Q. No, that's not correct?
A. I'm not offering an opinion.
Q. Okay.

You are also not offering an opinion regarding the intent of any shareholder of Vyera, are you?
A. No. I was asked -- you know what I was asked to do. I was asked to assess their distribution policies and practices.
Q. Now, let's talk about what you were asked to offer an opinion on.

You were asked to offer an opinion in this case with

respect to whether Vyera's distribution system and practices for Daraprim are consistent with pharmaceutical industry norms, correct?

A. Correct.

Q. My question for you is this: You told us yesterday that you did not undertake any formal analysis of the pharmaceutical industry in connection with your work on this project, right?

A. For nearly 45 years, that's all I did, was -- or it was an integral part of what I was doing with clients. I was assessing ways to distribute drugs in such a way that would maximize patient benefits and sales. And based upon all that experience, I attended over 20, maybe -- various meetings with the distributors, specialty distributors, specialty pharmacies, NCPDP, which is a group that sets standards for National Council of Prescription Drug Programs.

So because of my unique position of having all these positions — from market research, to brand manager, to distribution, to sales manager — all these things kind of give me a very, I believe, unique position that I could assess their practices based upon years and years of experience.

Q. I understand that, sir, but my question --

THE COURT: Excuse me, counsel.

So, Mr. Conroy, I appreciate this is your first time as an expert on the stand.

THE WITNESS: Thank you.

THE COURT: Is it the first time as a witness in a trial?

THE WITNESS: Yes.

THE COURT: Okay.

So, as frustrating as it may be, these are the rules: If you can answer a question fairly with a yes or a no, that's what you do. If you can't answer it fairly with a yes or a no, then briefly explain, you know, I don't know, I don't remember, yes with caveats, whatever it is to be truthful and accurate, but keep it brief.

Then, when this cross-examination is done, counsel for the plaintiffs have another chance to ask you questions, and, at that point, if they think it's important to me to understand more, they can ask you questions, so you can elaborate.

THE WITNESS: Fine.

THE COURT: Okay?

So frequently on cross-examination, they try to ask just yes-or-no questions. They don't succeed always, but that's often their aim. On redirect, there may be very broad open-ended questions. Okay?

THE WITNESS: Okay.

THE COURT: So listen with care to what you're asked.

THE WITNESS: All right.

THE COURT: Counsel.

MR. PARKS: Thank you, your Honor.

BY MR. PARKS:

Q. Sir, my question, again, is: You did not undertake any formal analysis of the pharmaceutical industry in connection with your work on this engagement, did you?

A. No.

Q. And we can agree, can't we, that because you didn't do any formal analysis of the pharmaceutical industry, your opinions in this case are not based on any formal analysis of the pharmaceutical industry?

A. That is true.

THE COURT: Excellent, excellent.

Q. You were also asked to offer an opinion in this case as to whether Vyera's distribution partners financially benefit from the Daraprim distribution system, correct?

A. Repeat it again?

Q. Sure.

You were asked to offer an opinion in this case as to whether Vyera's distribution partners financially benefit from the Daraprim distribution system, correct?

A. Correct.

Q. Sir, you did not conduct any formal study or analysis of the pharmaceutical industry in connection with developing your opinion on that question either, did you?

A. No.

Q. Your opinions in this case are based on your personal

experience and observations in the pharmaceutical industry as opposed to a formal analysis or study of the industry; isn't that correct?

A. That is correct.

Q. Sir, I'd like to ask you some questions now about your experience with pharmaceutical product distribution strategies.

During your time with GSK, it distributed about 20 specific brand-name drugs, correct?

A. At least that many.

Q. Over the course of your career, you have been involved in the product launches of about 25 different products, correct?

A. Yes.

Q. The product launches were not all specialty pharmaceuticals, were they?

A. No.

Q. They included some over-the-counter products, correct?

A. Yes.

Q. In fact, only five of the launches you have worked on involved specialty needs, correct?

A. Yes.

Q. Sir, how many different pharmaceutical products, approximately, are currently sold in the United States?

A. I couldn't give you a number, but it's in the thousands.

Q. I want to ask you some questions now, sir, about the distribution timeline, as you understand it, in this case.

In your expert report in this case, the first expert opinion you offered is that, "Some aspects of Vyera's Daraprim distribution system and practices are not consistent with industry norms."

Correct?

A. Correct.

Q. And the very first reason you offered for that conclusion is that Daraprim does not have the characteristics that warrant specialty distribution, correct?

A. Correct. Two or more is the general standard.

Q. Sir, my question for you is this: You understand, don't you, that Vyera was not the company that originally placed Daraprim into specialty distribution?

A. I understand that.

Q. Do you understand that a previous owner of Daraprim, a company called Amedra Pharmaceuticals, first moved Daraprim to specialty distribution?

A. That's the timeline I recall.

Q. So you do understand that Amedra was the company that moved Daraprim into specialty distribution?

A. I'm trying to remember if Impax actually did it first. Can I check my materials or --

Q. Well, let's see if we can refer to a paragraph in your deposition that would perhaps be helpful.

MR. PARKS: Justin, can we put up page 138 of

Mr. Conroy's deposition, starting at line 25 on to page 139. Actually, let's go back to -- well, that's great, 25 on the top of 139.

BY MR. PARKS:

Q. "Mr. Conroy, what is your understanding of who moved Daraprim to specialty distribution?"

Your answer: "It was not what I was asked an opinion on, but it could be argued that Amedra, and I mentioned that in my report somewhere."

"So is it your understanding that Amedra Pharmaceuticals moved Daraprim from," and then you interrupted with an answer, "They began the process."

Do you see that?

A. They did a study, so at that point in time, that was my statement.

Q. That's your understanding here today, is it not?

Do you have a different understanding here today of who started specialty distribution for Daraprim other than it was Amedra?

A. I believe -- from what I was rereading and rereading, I believe Impax actually began the process.

I mean, did I say Amedra? I meant -- did I say Impax?

Q. Yes. Just now, you said Impax.

A. Impax.

Q. You think Impax began specialty distribution of Daraprim?

A. Yeah, I think the facts will bear that out.
Q. Sir, the materials you identified in your expert report as materials on which you relied to form your opinions in this case include a document entitled "Specialty Pharmacy Provider Distribution Agreement Between Amedra Pharmaceuticals and Walgreens Dated February 23rd, 2015"; isn't that right?
A. Yes.
Q. And if we take a look at page 42 of your expert report, which is part of Appendix B, down there, about just below halfway on the page, there is that title of that document, "Specialty Pharmacy Provider Distribution Agreement Between Amedra Pharmaceuticals LLC and Walgreen Company, February 23rd, 2015."
Do you see that?
A. Yes.
Q. And at the top, this is the appendix of materials you rely on, if you look at Appendix B's title, right?
A. Yes.
Q. So this was one of the documents you relied on in developing your opinion in this case, right?
A. Yes.
Q. And you understand, from having relied on this document, that this agreement reflects the fact that Amedra Pharmaceuticals moved Daraprim into specialty distribution in 2015, don't you?

A. From what you're showing me, they signed an agreement with the previous -- ICS and with Walgreens.

Q. Sir, in your expert report, you also list, as a document on which you relied to develop your opinions, a marketing plan for Daraprim prepared by Amedra Pharmaceuticals in 2015, and we have the document on the screen. If you look here --

THE COURT: What's the number, counsel?

MR. PARKS: Oh, sure. It's DX 323.

THE COURT: Thank you.

BY MR. PARKS:

Q. And right here, in the middle of the page, it says, "Presentation: 2015 Sales & Marketing Plan - Daraprim."

Do you see that?

A. Yes.

Q. So that was a document you were familiar with from your work on this case when you prepared your opinion, correct?

A. Yes.

Q. Now, let's take a look at that document. This is DX 327.

You recognize this from your work on the case?

A. Yes.

Q. Let's take a look, sir, at the third page of that exhibit.

Now, on this page, Amedra explains in this presentation --

THE COURT: Excuse me, counsel. Is this document in evidence?

MR. PARKS: I do not know if it's on the evidence list. But my view would be that it's cross-examination. Am I not entitled to use any document with the witness on cross?

THE COURT: Well, I don't know about any, but you are entitled to use documents on cross that weren't on the exhibit list as evidence in chief; however, you can't read from it unless it's in evidence. So you can use it to refresh. I'm just trying to understand what's in the record and what isn't.

MR. PARKS: Fair enough. I will ask the question from a refresh his recollection standpoint since he has identified this as a document on which he relied to develop his opinion.

BY MR. PARKS:

Q. Sir, does this page of this document refresh your recollection that Amedra began considering moving Daraprim from open distribution to specialty distribution in 2014?

A. Yes.

Q. You're aware, from reviewing this document in the course of your work, that Amedra identified a number of benefits of moving Daraprim from open distribution to specialty distribution, correct?

A. These were their recommendations on this slide.

Q. And you were aware, from reviewing this document in connection with the preparation of your report, that Amedra identified a number of benefits associated with moving Daraprim into specialty pharmacy distribution, correct?

A. That's what this document says, yes.
Q. One of the benefits identified by Amedra of moving Daraprim into specialty distribution was a reduction in distribution fees, correct?
A. Reported reduction, and until you negotiate distribution fees, you don't know what they'll actually be.
Q. But you understood, from reviewing this document, that Amedra identified a reduction in distribution fees as a potential benefit of this, correct?
A. A potential reduction and, therefore, a potential benefit in that single line.
Q. Another potential benefit that Amedra identified from moving --
MX. BLACK: Objection, your Honor. This is going beyond refreshing recollection.
THE COURT: Sustained.
MR. PARKS: I will rephrase the question, your Honor.
BY MR. PARKS:
Q. Do you recall that another benefit that Amedra identified in moving Daraprim into specialty distribution was improved price management?
A. That was their conclusion on this slide.
Q. Do you recall, from your review of this document, that another benefit Amedra identified from moving -- or potential benefit that Amedra identified from moving Daraprim into

specialty distribution was greater visibility of inventory, including returned goods management?

A. Yes.

Q. Do you recall, from your review of this document in the course of preparing your report, that another potential benefit that Amedra management identified, in moving Daraprim into specialty distribution, was the ability to provide more resources to patients, caregivers, and healthcare providers?

A. Potentially, yes.

Q. And do you remember that another benefit that Amedra management identified from moving Daraprim into specialty distribution was more transparency as to how the product is being prescribed and what the concomitant therapies may be prescribed with it?

A. Potentially.

Q. Now, you're aware, from reviewing this document, that Amedra selected Walgreens specialty pharmacy as its preferred distribution partner, correct?

A. Correct.

Q. And although you were aware of this document when you developed your opinions in this case, you did not address this document in your expert report in this case, did you?

A. Not directly, but in a lot of the other arguments, I clearly tried to elaborate on why these are -- the degree of potential -- potentiality, if that's such a word.

Q. Your analysis, sir, does not attempt to examine whether any of the benefits Amedra identified as potentially flowing from specialty distribution of Daraprim were actually realized, does it?

A. Repeat the question again?

Q. Sure.

Your analysis does not attempt to examine whether any of the benefits Amedra identified as potentially flowing from specialty distribution of Daraprim were actually realized, does it?

A. Only in regard to what I was -- if I chose one, such as -- how did they say it?

There was ample discussion, from my experience, that these applied to the six things that later on -- that these things could lead to the later on things that Vyera did, frankly.

Q. Sir, do you recall that you testified at your deposition that the reason you did not address this document specifically in your report was that you were asked to opine on Vyera, not Amedra?

A. Yes.

Q. Did Amedra Pharmaceuticals sell Daraprim directly to Vyera?

A. In my best recollection.

Q. Sir, didn't Amedra Pharmaceuticals sell Daraprim to Impax Laboratories in March of 2015?

A. My recollection is Impax -- Impax bought the product first from GSK back in about 2012 — I can't bring up the exact date — and then Amedra -- it was transferred to Amedra. Check me if I'm wrong on that.

Q. Do you mean Daraprim was transferred -- I'm sorry, I don't understand what you said there. And then Amedra was transferred?

A. What I recall is that Impax acquired it from GSK, and then it was transferred to Amedra, and then Amedra, in 2015, there were discussions, I believe, in April and then maybe in August, and actually the transfer or sale, whatever you referred to it as, went to Vyera at that point.

Q. Sir, just to refresh your recollection on this, can we take a look at your expert report that's DX 323 at paragraph 41 on page 13.

Does that refresh your recollection that at least, in your own expert report, you had said that in March 2015, Impax Laboratories acquired Daraprim as part of its $700 million acquisition of Amedra's parent company?

A. Can you put it in better context and include previous paragraphs?

Q. Sir, my question for you is: Isn't --

A. That is what I said, yes.

Q. Okay.

And the proper sequence of events here is that GSK

transferred this product to Amedra, and Amedra then transferred it to Impax, correct?

A. That's what it said here, yes.

Q. That's what happened, isn't it?

A. Yes.

Q. Now, after acquiring Daraprim from Amedra in March of 2015, Impax continued distributing Daraprim through specialty distribution, didn't it?

A. Yes.

Q. So when Vyera acquired Daraprim from Impax, Vyera inherited the specialty distribution model for Daraprim that was developed by Amedra and continued by Impax, didn't it?

A. For a short period of time, yes.

Q. And, sir, because you were asked to opine on Vyera, not Amedra or Impax, you did not spend a lot of time on the way Amedra or Impax distributed Daraprim in developing your opinions in this case; isn't that right?

A. That is correct.

Q. After --

A. I'm familiar with it, but I didn't spend a lot of time on it.

Q. After Vyera acquired Daraprim, it actually added more distributors than Amedra or Impax had for Daraprim, didn't it?

A. Yes -- well, they dismissed ICS, who I have actually worked with at one time, and they added ASD, which is Amerisource

specialty distributor, and they added a few other people, but then they added many restrictions on the products.

Q. Sir, I'm asking you about the number of distributors, they went up after Vyera acquired Daraprim, didn't they?

A. Yes.

Q. And you recognize, don't you, that Vyera added these additional distributors to make it easier for customers to buy Daraprim?

A. They had contacted, I believe it was, Walgreens -- was it Walgreens? They had contacted --

Q. Sir, my question was: They added these distributors to make it easier for customers to buy Daraprim, didn't they?

A. That could be a possible outcome. I can't -- okay.

Q. So let's take a look at your deposition, page 178, line 20. You were asked: "So to cut to the chase, is it your opinion that Vyera added these distributors to make it easier for customers to buy the product?"

And your answer was, "Yep," and then you went on.

Correct?

A. I said they needed government, which is the VA, et cetera, they needed Walgreens, so -- and they needed Optime. So, yes, that's what I said.

Q. You explained earlier that you're offering opinions here about pharmaceutical industry norms, right?

A. Yes.

Q. And your opinions are based on your personal experience, right?
A. Yes.
Q. Your experience, your personal experience, does not include anything to do specifically with the distribution of Daraprim, right?
A. No, but the norms definitely are, in my experience --
THE COURT: If you can answer fairly with a yes or a no.
THE WITNESS: Okay. Repeat the question, please.
BY MR. PARKS:
Q. Sir, your experience does not include anything to do specifically with the distribution of Daraprim, does it?
A. Daraprim was in my purview, yes, so...
Q. Sir, your experience with specialty distribution is limited to five products, isn't it?
A. That I recall, yes.
Q. And you didn't find it relevant to your analysis of industry norms that Vyera was not the first, not even the second, but the third company to distribute Daraprim through specialty distribution, did you?
A. Repeat the first part of the question?
Q. Sure.
You did not find it relevant to your analysis of industry norms that Vyera was not the first, not the second,

but the third company to distribute Daraprim through specialty distribution, did you?

A. I did in the sense that when you inherit -- when you purchase a product, you do not have to follow the previous company's distribution strategy. So it was part of the overall thought process.

Q. Do you remember being asked in your deposition whether those facts were relevant, and you said, "Is it relevant? Not necessarily"?

A. Yes, as you're quoting me.

MR. PARKS: That's all the questions I have for this witness at this time. Thank you.

THE COURT: Will there be redirect? I'm not rushing you, I just want to know.

MX. BLACK: Perhaps, your Honor.

THE COURT: Thanks. Take your time.

(Pause)

REDIRECT EXAMINATION

BY MX. BLACK:

Q. Good morning, Mr. Conroy.

A. Good morning.

Q. Do you recall earlier counsel asked you about your experience with specialty drugs?

A. Yes.

Q. And do you recall counsel pointing out that you have

experience with only five drugs with specialty needs?
A. That I recall, yes.
Q. Could you describe for the Court your experience with specialty drugs over the course of your 45 years of experience?
A. You can -- the first one -- well, if you meant drugs that actually go into distribution through specialty, we had drugs that, like Retrovir, where specialty was -- Retrovir was for HIV treatment. As a matter of fact, it's the first one. We considered putting it in specialty, but it was a tablet, and the AIDS -- AIDS was growing rapidly, so we put it in open distribution, so any local pharmacy, where an AIDS patient might need it, could get it.

I also worked on Flolan, which is a high -- very, very high touch complicated cold chain. It's for primary pulmonary hypertension. Once you went on Flolan, if you were a patient, and -- and the tightest restrictions, okay, that you would die. So we had to build a distribution system through a specialty distributor and pharmacy — Accredo, I believe — so that patients were absolutely assured that they would get their drug in a timely fashion, and it could be very extremely adverse if they did not get that.

And even though it was in specialty, we didn't put any major restrictions other than that Accredo had it, and Accredo -- these patients need it, it's very complex, needed a lot of high touch, and those were the types of issues we were

addressing.

I also worked on Wellcovorin and -- which was a specialty -- could have been a specialty — it actually is a specialty today — but it's open distribution, almost exclusively.

Lotronex, which was an IBS drug at GSK, and when we launched it, it was open distribution. It was a tablet. And what happens, we had a series of side effects that the FDA called to our attention. We immediately pulled the drug from the market. They developed a REMS.

Are you familiar with a REMS? Okay.

It's a way to mitigate risk or lower risk. So we had a REMS on Lotronex.

And then I currently have a client with an asthma drug -- not an asthma drug -- for agitation associated with bipolar schizophrenia, and it's both an -- because of my experience, it's a combo drug. It's in a specialty wholesaler McKesson Specialty, and it's also an open distribution with always the goal of making it highly likely that a patient could get their drug in an extremely timely fashion, and if need be, in a local pharmacy where they have a relationship with a pharmacist.

Q. Is your knowledge of specialty distribution limited to the five drugs you directly work with?

A. No, because as I -- basically, I was a consultant for

roughly 2000 to current. I may have met with other companies that -- I remember I helped small -- basically small startup pharmaceutical companies commercialize their drugs. So in every one of these instances, the distribution techniques, rules, using industry norms, were always discussed to find the optimal way to maximize profits, to deal with whether it was an IV drug or a tablet or the other variables.

So you're constantly discussing the distribution system, and that's where all my other experience kind of really helps out.

Q. Thank you, Mr. Conroy.

Do you recall now being asked some questions about Amedra's slide deck in DX 327?

A. The one we looked at earlier?

Q. Yes.

A. Yes.

Q. Do you recall what Amedra predicted with respect to sales volume after the transition to specialty?

A. Yes. It actually declined. And, actually, the decline was slightly more for specialty than it was for retail.

Q. What does it tell you about benefits of specialty for Daraprim?

A. We were on the slide earlier. I'm...

Q. Let me rephrase.

A. With that information, one would consider the fact that it

was specialty the best distribution system for Daraprim. It wasn't high touch. It had been on the market since 1953. It wasn't cold chain, it wasn't REMS, it wasn't all the other hallmark -- basically hallmark things, and it wasn't a new entry, it was a very old drug, and all my background suggested it was a reasonably safe drug, and prescribers were quite familiar with the disease and how to treat it because, by and large, the HIV treaters were the predominant group that used it because toxoplasmosis is an opportunistic infection.

Q. What does Amedra's predicted volume decline after transition to specialty tell you about patient access to Daraprim?

A. Well, their conclusion was it might -- I don't have it in front of me, but my recollection was it -- it potentially might -- oh, access?

Because in specialty, you're going to have fewer places to shop or -- shop for -- to get your prescription filled. It would probably deny access. And it never addressed what Vyera actually went on ahead and did.

Q. Let's talk about that.

You recall being asked questions about Vyera adding distributors after it acquired the product?

A. Uh-huh.

Q. How did addition of distributors affect distribution restrictions?

A. Repeat that question, so I can understand?

Q. Earlier you started talking about restrictions and how a transition to specialty did not address the restrictions.

Do you want to tell us more about the restrictions that Vyera used?

A. Okay. They had customer restrictions, okay, which they very limited -- Vyera had, correct?

Specifically, you're referring to Vyera?

Q. Yes.

MR. PARKS: Your Honor, I believe this is beyond the scope of my cross-examination.

THE COURT: It's not beyond the scope, but I think the question could be more focused.

Can you place a question to the witness so he knows what information you wish to elicit?

MX. BLACK: Yes, your Honor.

THE COURT: Counsel on cross-examination mentioned that when Vyera acquired Daraprim, it increased the number of distributors.

Do you remember that question?

THE WITNESS: Yes.

THE COURT: Did that increase in the number of distributors, in your mind, increase access to the drug for the patient population suffering from toxoplasmosis?

THE WITNESS: That alone would have the potential of

doing that, your Honor, but the addition of restrictions --

THE COURT: Did it in this case?

THE WITNESS: -- counteract that.

THE COURT: Did it in this case? Did it increase in the number of distributors in this case? Did what Vyera did in this case, when it increased the number of distributors, increase the access to the drug?

THE WITNESS: Based upon the sales results, I would say no.

THE COURT: Why not?

THE WITNESS: A drug such as Daraprim with toxo -- you need rapid access, and so even though they increased some distributors, they closed down -- their restrictions affected retail pharmacy. AIDS patients often have a very good relationship with a local pharmacy and who counsels them, knows their disease, probably knows their doctor, as opposed to on the phone, and you're dealing with a specialty pharmacy, which is very -- you don't know who the person is, they don't know who you are — maybe you've had that experience, I have — it can be very -- it can be a conundrum trying to figure out, this guy doesn't know what I'm talking about, as a patient getting my drug.

So when you get doubts in taking a drug, oftentimes you don't take it. So these added distributor -- to answer your question, just by adding, I think it was a very limited

addition, that it would not necessarily result in increased access.

Does that help?

BY MX. BLACK:

Q. Besides adding distributors, did Vyera do anything else to restrict access to patients?

A. They put a bottle --

MR. PARKS: This is beyond the scope of my cross, your Honor.

THE COURT: I think, as I understand it, the point you were making on cross was, Vyera added distributors to increase access to the drug, so you opened the door for this witness to explain whether or not Vyera took actions to increase access to the drug. And counsel will inquire, or not, at her choice.

Place a question, counsel, if you have one.

BY MX. BLACK:

Q. So, Mr. Conroy, did Vyera do anything, after it acquired Daraprim, to restrict access to Daraprim?

A. Yes. They put purchase limits on it. They did intensive monitoring and purchase limits of five bottles so that -- I can expand on that, but that simply means somebody could run out of stock. It's more likely. Today's modern open distribution system, wholesalers' open distribution, wholesalers deliver same day in big cities like New York and next day, the Amazon mentality, if you will. They put purchase -- so purchase

limits, this doesn't really affect the patient, but they excessively monitored all purchases, they reduced the number of customers, they pulled out, I think, roughly 17,000 fewer outsources -- not outsources, potential places to buy drug -- the local pharmacies, basically.

So none of those things help improve access. It's kind of like on the front side, you can have more distributors; on the backside, you give the distributors less product, you give the patients less access to pharmacies. So, in my experience, and that study by Amedra kind of shows, they're going to have a decline in sales, when most of us in the industry, if not all of us, work very hard to increase sales rather than monitor sales and put restrictions such that you could decrease sales.

MX. BLACK: Thank you, Mr. Conroy.

Thanks, your Honor. These are all the questions I have.

THE COURT: Any additional cross?

MR. PARKS: Very, very briefly, your Honor.

RECROSS EXAMINATION

BY MR. PARKS:

Q. Sir, you just talked about declining sales for Daraprim.

You haven't done any analysis of the reasons for those decline in sales, such as decline in incidence of toxoplasmosis, did you?

A. Not medical reasons.

MR. PARKS: Thank you. Nothing further.

THE COURT: So, Mr. Conroy -- I'm sorry, any redirect?

MX. BLACK: No, your Honor.

THE COURT: Mr. Conroy, you made a distinction in the answer you gave recently between specialty distribution and open distribution?

THE WITNESS: Yes.

THE COURT: You can have specialty distribution, but you can also, at the same time, have open distribution?

THE WITNESS: Yes. It's a spectrum.

THE COURT: So explain, please, how you're using those terms and how you can have both at the same time.

THE WITNESS: Okay. The left-hand side, the extreme open distribution, is you sell to all -- I call them wholesalers -- the big ones — McKesson, Cardinal, AmerisourceBergen, there are some other ones, but about 90 percent of them are in place. They specialize in everyday deliveries to drugstores. They also have OTC items, over-the-counter items, and then within that, you could put -- then you start stepping down. You could design a restriction as to an open distribution for some reason. You may not have a contract with the government, but I don't think you'd ever restrict on that basis.

The other extreme side is something like I mentioned

Flolan — that was for the -- I think it was only a thousand patients, but that was tightly restricted simply because it was cold chain, and if a patient didn't get their drug, and we wind up with all the expertise of Accredo at that time, so that patients were absolutely assured. Having said that, using kind of the middle example, Atticu, which I'm working on now, because there are sites -- it's for psychiatric patients, okay. So I use a mixture of distributors. McKesson Plasma and Biologics is a -- it's kind of like ASD, it would be the equivalent of ASD in this conversation. They have a lot of relationships where it's very highly likely that Atticu would be needed and needed in a timely fashion.

At the same rate, many of these patients -- and, also, McKesson deals with the government, so that opened that up. Their prime vendor, it's called.

But then there's plenty of these patients in small towns, big cities, that just want to go to their local pharmacy to get it.

Now, it was a REMS drug, so we had to put a restriction on it, we had to be REMS certified through a set of obligations. So, there you have an open -- I certified the wholesalers, but only after they became REMS certified.

Does that make sense to you?

(Continued on next page)

THE WITNESS: There are other mixtures of I think, bio -- the one distributor they use, there is a specialty distributor. 50 percent of their customers. There were no restrictions or suppliers. There were no restrictions on their drugs and then 50 percent had some specialty restrictions.

THE COURT: Open distribution, as you are using that term, means that any drug wholesaler with whom you have a contract can purchase the product and distribute it to any kind of pharmacy or medical institution.

THE WITNESS: To a licensed pharmacy or a doctor with what is called a medical education number, yes.

THE COURT: Specialty distribution, as you are using that term, in contrast, means what?

THE WITNESS: It means that -- in the broadest context, specialty distributors usually have a market segment, like hospitals. Like the VA, like a set of specialty pharmacies, Walgreens Specialty pharmacy, so they -- because of their focus on maybe a disease state or because of a focus on hospitals, that they could be the optimal solution that's related to the patients, but it would be the optimal solution for getting drugs to that. It could be a REMS drug. They know how to handle cold chain products. They have to be refrigerated. They have to be carefully monitored.

Generally, one of the biggest reasons you use really kind of a specialty would be really complex drugs. There is a

reference in my statement that 70 percent of the physical volume is open distribution with a few restrictions, if any, and 30 percent is specialty.

But on the dollar wise now it's about 50/50 because the specialty drugs that go into specialty are usually ones we referenced in my document, they were approved in 2018. The recently approved drugs, sometimes like the vaccines, they are approved without really large studies, but the evidence was such, so they will approve them. By keeping it in restricted distributions is a specialty and only certain types of pharmacies that they can work with the doctors who don't have -- like the experience they have with Daraprim is years and years and years. So doctors who use it are very, very familiar with it.

The newer specialty drugs that are high touch, high cost or have some of these characteristics, specialty -- interacting with other drugs, immunology, cancer drugs, MS drugs, a lot of what you see on TV, by having to tie tightly with a pharmacy system, a specialty pharmacy that has those abilities to truly help manage that patient and the side effects and the indications and all the complexities of the new drugs you would consider -- in my opinion, definitely consider them for specialty.

THE COURT: Counsel, do you have any questions for this witness based on the questions I have placed to him?

MX. BLACK: No, your Honor.

MR. PARKS: No, your Honor.

THE COURT: You may step down.

(Witness excused)

THE COURT: Next witness.

MR. MEIER: Your Honor, the government calls as its next witness Manish Shah. He's with Cerovene. My colleague, James Weingarten, will be handling that for the government, your Honor.

THE COURT: Mr. Shah, if you could come up here, please.

Mr. Shah, if you could come up to the front of the courtroom, please. No need to rush. Take your time.

If you could take the stand here and remain standing. If you could come up here and take that stand.

MANISH SHAH,

called as a witness by the Plaintiffs,

having been duly sworn, testified as follows:

THE COURT: You may be seated. You go pull that chair up. That mic can be adjusted so it is under your chin and sort of down. There you go. We will see if that works.

You are being handed your affidavit, which has been marked as GX-8011. I'd like you to turn to the last page, which is, I believe, page 19.

THE WITNESS: Yes.

THE COURT: Did you authorize your electronic signature to be added to that document?

THE WITNESS: Yes.

THE COURT: Before you gave that authorization, did you read the entire document with care?

THE WITNESS: Yes.

THE COURT: Do you swear to the truth of the contents?

THE WITNESS: Yes.

THE COURT: Any objection to receipt of GX-8011?

MR. CASEY: Your Honor, no objection.

THE COURT: Thank you. It is received.

(Government Exhibit 8011 received in evidence)

THE COURT: Cross-examination.

MR. WEINGARTEN: Mr. Shah, I believe you are allowed to take off your mask during the questioning, if you'd like.

THE COURT: Yes, Mr. Shah. I should have explained that. Thank you, counsel.

Our courtroom has had ventilation testing and there is a swift air exchange here. You and counsel at the podium are permitted to take off masks. Thank you.

CROSS-EXAMINATION

BY MR. CASEY:

Q. Good morning, Mr. Shah.

A. Good morning.

Q. My name is Chris Casey. I represent Mr. Shkreli in this

proceeding. I have questions for you this morning.

First, Mr. Shah, Cerovene was initially getting its pyrimethamine API from a company called Ipca, correct?

A. Yes.

Q. And Ipca was subject to an import alert in 2015 forcing Cerovene to find another source of API, correct?

A. Yes.

Q. Now, in your written direct testimony you discussed Cerovene's attempts in 2015 and 2016 to obtain pyrimethamine API from Fukuzyu, correct?

A. Yes.

Q. That's at paragraphs 21 through 28, correct?

A. Yes.

Q. Those efforts were unsuccessful, correct?

A. Yes.

Q. You were not able to enter an API supply agreement with Fukuzyu, correct?

A. Yes.

Q. In 2016, Cerovene began negotiations with a company called RL Fine to supply pyrimethamine API, correct?

A. Yes.

Q. Now, Cerovene did not speak with any API suppliers about pyrimethamine API other than RL Fine and Fukuzyu in 2015 and 2016, correct?

A. Yes.

Q. And Cerovene made no attempt in 2015 and 2016 to identify other manufacturers that were providing pyrimethamine powder in markets outside the United States, correct?

A. Can you repeat the question, please.

Q. Sure.

Cerovene made no attempt in 2015 or 2016 to identify other manufacturers that were providing pyrimethamine powder in markets outside the United States, correct?

A. Well, we made some other attempts by talking to the colleagues and friends in the industry and see if anybody else is producing pyrimethamine API, and we didn't find anybody who could manufacture pyrimethamine API.

Q. Do you recall being asked this question at your deposition, Mr. Shah? Your deposition was on December 17 of 2020. Do you recall that deposition?

A. I don't recall.

MR. CASEY: Can we have the deposition transcript up, please. At page 230, starting at line 21 there.

Q. The question is asked: Did you make any effort to identify other manufacturers that were providing pyrimethamine powder in markets outside the U.S.? You answered no, correct?

A. Yes.

Q. That testimony was truthful, correct?

A. Yes.

Q. Cerovene made no attempt in 2015 and 2016 or 2016 to

identify other manufacturers that were supplying pyrimethamine powder for the compounding industry in the United States, correct?

A. We didn't make any effort.

Q. On November 16 of 2016, Cerovene and RL Fine entered into a supply agreement, correct?

A. Yes.

Q. And the supply agreement provided that RL Fine would exclusively supply Cerovene with pyrimethamine, correct?

A. Correct.

Q. Now, you said in your direct testimony at paragraph 32 that exclusivity "made economic sense to keep other companies from free writing on Cerovene's investment in getting RL Fine qualified to supply pyrimethamine in the United States," correct?

A. Yes.

Q. But when were you asked in your deposition in this case that the reasons why Cerovene wanted exclusivity in its agreement with RL Fine, you didn't say anything about free writing, did you?

A. I don't recall.

Q. Maybe we can pull out the deposition. Maybe it will refresh your recollection. Let's go to the deposition at page 237: You are asked there starting at line 18: What about exclusivity running in the other direction? In other words,

why was it important to Cerovene that RL Fine would only supply Cerovene with API for a period of years? You answered at line 24: Well, it's part of the overall picture of how you deal with the specific project and -- product and company, right. We wanted to be sure that RL Fine --

THE COURT: Slow down.

Q. We wanted to be sure that RL Fine is able to supply us with the commercial quantities of the API that we needed.

Does that refresh your recollection, Mr. Shah?

A. That's what I said at the time.

MR. WEINGARTEN: Your Honor, I am not sure if it is refreshing or impeaching. If it's impeaching, I respectfully suggest that the rest of the answer be read as well.

THE COURT: Counsel, you may complete the quotation.

MR. CASEY: I didn't hear the rest of the objection.

THE COURT: Sorry, counsel. It was that you had cut off reading the complete answer.

MR. CASEY: I'm happy to.

Q. Your answer goes on in your deposition: When I visited the facility, they really don't have a very big facility to produce the API, so we wanted to make sure that if you are going to waste time and money and going to do all this work, we get a commercial supplies. You said that, correct?

A. Yes.

Q. Again, there is nothing in your answer at the deposition

that talked about other companies free writing on your investment?

A. No.

Q. You signed the agreement with RL Fine on behalf of Cerovene, correct?

A. Yes.

Q. And you also signed on behalf of Cerovene the major amendment for Cerovene's Daraprim ANDA identifying RL Fine as Cerovene's new API supplier, correct?

A. Yes.

Q. That was on April 2, 2017?

A. Yes.

Q. So it was approximately six months from the time that you signed the API supply agreement to the time that you submitted the major amendment identifying RL Fine as the new API supplier, correct?

A. Yes.

Q. In 2016 and 2017, RL Fine delivered pyrimethamine API to Cerovene, correct?

A. Yes.

Q. Those orders provided Cerovene with enough API to complete bioequivalency testing and to support the commercial launch of Cerovene's generic Daraprim product, correct?

A. Yes.

Q. After Cerovene's ANDA was approved, Cerovene also ordered

additional pyrimethamine from RL Fine that was delivered in April 2020, correct?

A. Yes.

Q. And that pyrimethamine API was provided under the terms of the November 16, 2016 supply agreement between Cerovene and RL Fine, correct?

A. Yes.

Q. So every time that Cerovene has placed an order for pyrimethamine API under the November 16, 2016 supply agreement, RL Fine has provided it, correct?

A. Yes.

Q. Now, Mr. Shah, I am going to switch now to talk about some of the filings and letters you sent to the FDA, OK?

A. OK.

Q. First, before we get to that, in December 2017, the FDA required Cerovene to redo its bioequivalence testing using the RL Fine API, correct?

A. Yes.

Q. On January 22, 2018, Cerovene asked the FDA to reconsider that decision, correct?

A. Yes.

Q. And you signed the letter that went to the FDA on behalf of Cerovene, correct?

A. Yes.

Q. Then two months after submitting that request for

reconsideration, Cerovene sent a follow-up letter to the FDA demanding an answer one way or the other granting or denying your request for reconsideration, correct?

A. Yes.

MR. CASEY: Can we have DX-376 up. Thank you.

Q. Mr. Shah, do you see what's on the screen now?

A. Yes.

Q. That's DX-376. Do you recognize that document?

A. Yes.

Q. Is that the letter that you sent to the FDA?

A. Yes.

MR. CASEY: If we can go down to the last full paragraph on the page. Right there.

Q. You see where it says: If Cerovene were to simply acquiesce and conduct the newly requested studies whose necessity Cerovene is challenging, Cerovene would have to spend over $600,000 in RLD acquisition costs alone to acquire the requisite five bottles of Daraprim. Do you see that?

A. Yes.

Q. Then you go on to say: This $600,000 RLD acquisition cost expenditure would be in addition to the many additional hundreds of thousands of dollars that Cerovene would spend conducting the newly requested bioequivalence studies.

That was you stating that to the FDA in your letter, correct?

A. Yes.

THE COURT: Counsel, can I just ask, is DX-376 in evidence?

MR. CASEY: Your Honor, I should have offered it. The defendant offers DX-376 into evidence.

THE COURT: Any objection?

MR. WEINGARTEN: No objection, your Honor.

THE COURT: Received.

(Defendant's Exhibit 376 received in evidence)

MR. CASEY: Thank you.

Q. Mr. Shah, Cerovene did not want to commit the $600,000 it would have to spend acquiring RLD until the FDA acted on its request for reconsideration, correct?

A. You can read simply what we are saying here. We are saying that -- what I'm trying to say is that, in answering the question that you have is what we are simply saying FDA, there is going to be an additional cost of $600,000, approximately, and then there is additional cost of bioequivalence study. So FDA must reconsider what they were restating in the company response letter of 2017. That's what we are saying to FDA.

Q. To my question, Cerovene did not want to commit the $600,000 it would have to spend acquiring RLD until the FDA acted on its request for reconsideration. Isn't that correct?

A. Well --

Q. Mr. Shah, could you just answer that. That's a yes or no

question. Is that correct, or not?
A. Yes.
Q. Now, in June 2018, about six months after you submitted the request for reconsideration, the FDA rejected Cerovene's request, correct?
A. Yes.
Q. Now, I am going to switch topics now and talk about Cerovene's efforts to obtain RLD. Do you know what I mean when I say RLD?
A. Yes.
Q. That's reference listed drug, correct?
A. Correct.
Q. So you were seeking a Daraprim reference listed drug to do your bioequivalence test after the FDA ordered you to, correct?
A. Yes.
Q. You led Cerovene's efforts to acquire new RLD samples after the FDA required Cerovene to perform new bioequivalence testing, did you?
A. Yes.
Q. Cerovene understood that it needed a minimum of five 100-count bottles of Daraprim RLD to do the testing and meet the sample retention requirements, correct?
A. Yes.
Q. In February 2018, Cerovene and Dr. Reddy's engaged Reliant Specialty to acquire five bottles of Daraprim, right?

A. Yes.
Q. And Reliant represented that it could acquire five bottles and quoted a price of $110,000 per bottle, correct?
A. Yes.
Q. Cerovene placed an order with Reliant for $550,000 for five bottles, correct?
A. Yes.
Q. Reliant was only able to procure one bottle, correct?
A. Yes.
Q. And the delivery of that one bottle was on June 4, 2018, correct?
A. Yes.
Q. Now, in February 2018, before you placed the order with Reliant, Dr. Reddy's identified ProSupplier, a Swiss procurement company, as being able to supply Daraprim samples, correct?
A. Yes.
Q. And ProSupplier is the firm that many months later, in November 2018, ultimately supplied Cerovene with a Daraprim samples that you used to do your bioequivalence testing, correct?
A. Yes.
Q. In February 2018, Dr. Mukhopadhyay of Dr. Reddy's offered to help Cerovene place orders for RLD samples, correct?
A. Yes.

Q. And Dr. Mukhopadhyay stated to you in an e-mail on February 20, 2018: "Can we work with ProSupplier and order for Cerovene? Cerovene will pay us for the RLD. I am suspecting the suppliers are not taking the orders seriously as Cerovene is a smaller company."

Do you remember that e-mail?

A. I don't exactly recall the e-mail, but, yes. There are e-mails between me and him.

MR. CASEY: Why don't we get GX-3395, please.

Q. I am showing you on the screen there what's marked as GX-3395. It's an e-mail chain.

MR. CASEY: If you could go down to page 2, please.

Q. Do you see the e-mail from Dr. Mukhopadhyay, February 20, 2018 e-mail?

A. Yes.

Q. He says: Hi, Manish. This is an e-mail that was addressed to you, correct?

A. Yes.

Q. Among others in Dr. Reddy's?

A. Yes, um-hum.

Q. It says: Hi Manish. As we still do not have the RLD from Espee after more than a month, I think we should cancel the PO and work with ProSupplier. Then it goes on: Ramesh Malli, can we work with ProSupplier and order for Cerovene. Cerovene will pay us for the RLD. I am suspecting the suppliers are not

taking the order seriously as Cerovene is a smaller company. We may have better chance of getting the RLD quickly if DRL orders on behalf of Cerovene.

Do you see that?

A. Yes.

Q. Does that refresh your recollection of seeing this e-mail before?

A. Yes.

Q. In February 2018, Dr. Reddy's encouraged Cerovene to work with ProSupplier to obtain the Daraprim samples needed to redo the bioequivalence testing, correct?

A. Yes.

Q. And Cerovene had evaluated ProSupplier as a source of Daraprim RLD but decided to remain with Reliant because of Reliant's representations that it could get five bottles of Daraprim RLD, correct?

A. Yes.

Q. Now, you don't have any reason to believe that ProSupplier could not have supplied Daraprim RLD to Cerovene in February 2018 if Cerovene had placed an order with ProSupplier at that time, correct?

A. Correct.

Q. It was not until September 2018, more than six months after Dr. Reddy's had first suggested that Cerovene contact ProSupplier, that Cerovene agreed to have Dr. Reddy's place a

purchase order with ProSupplier, correct?
A. Yes.
Q. That order was for three 100-count bottles of Daraprim rather than five, correct?
A. Yes.
Q. And it was Dr. Reddy's, not Cerovene, that actually placed that order with ProSupplier, correct?
A. Yes.
Q. Dr. Reddy's placed that order after Cerovene had submitted a request to the FDA for a waiver to permit Cerovene to complete the bioequivalence testing and satisfy the retention requirements with just three bottles instead of five, correct?
A. To the best of my recollection, yes.
Q. So the order was placed after Cerovene made the waiver request of the FDA, correct?
A. I think so.
Q. I can refresh your recollection on that. You say you don't recall exactly the date of the FDA request?
A. I don't remember the exact dates because it's just that we were trying to get the FDA an answer -- we were working with the FDA to see if FDA can change their retention quantity requirement. At the same time we were working with different suppliers, like Reliant Pharmacy, ProSupplier and any others that Dr. Reddy's suggested. They were happening at the same time. I am not sure they were connected in terms of making a

decision of which supplier to go.

Q. My question, Mr. Shah, is very simple, when these events happened. If I could direct your attention to your written direct testimony at paragraph 64. Do you see that, paragraph 64?

A. Yes.

Q. That letter to the FDA was in July 2018, correct?

A. Yes.

Q. And the request or, rather, the order that Dr. Reddy's placed for the RLD was in September 2018, correct?

A. Yes. Um-hum.

Q. But the order was placed before the FDA had granted the waiver, correct?

A. Order to ProSupplier?

Q. Yes.

A. Yes.

Q. That waiver wasn't granted until April 2019, correct?

A. Correct.

Q. So at the time that Dr. Reddy's placed the order with ProSupplier for three bottles of Daraprim RLD rather than five, Cerovene was still required, under the FDA rules, to conduct the bioequivalence testing using five bottles, correct?

A. Correct, yes.

Q. Now, you say in paragraph 62 of your written direct that you, quote, would have preferred to purchase more than three

bottles from ProSupplier, but it was your, quote, understanding that ProSupplier could acquire only three bottles.

Do you see that?

A. Yes.

Q. My question to you, Mr. Shah, is, what is the basis for that understanding?

A. I can't exactly tell you what was the basis. These questions happened between Dr. Reddy's and us. Looking at the scenario where their brand RLDs is difficult to get, and all the circumstances leading to that, it's just difficult to get more bottles. These are the discussions that happened between different parties. And it just seemed like five bottles is difficult to get.

Q. So did ProSupplier tell Dr. Reddy's or Cerovene that there was a limit on how many bottles it could provide and that limit was three?

A. I don't recall exactly. But I am sure there was some discussions about that between ProSupplier and Dr. Reddy's.

Q. Mr. Shah, I am trying to get an understanding -- the question is, do you have an understanding that ProSupplier could acquire only three bottles? What was that based on?

A. Like I said, it's based on the discussions that were happening between the different parties at that time. Primarily, I was talking to Dr. Reddy's, and Dr. Reddy's contact was ProSupplier and that was the feeling I got, that

they can only get three bottles.

Q. Did anyone from ProSupplier tell anyone at Dr. Reddy's or Cerovene that it could only procure three bottles?

A. Not that I'm aware of, no.

Q. You really didn't have an understanding that ProSupplier could acquire only three bottles. That's not accurate, correct?

A. I can't tell you whether it is accurate or not. But that was my understanding, is that it's difficult to get the bottles.

Q. Mr. Shah, this is a sworn statement that you provided to the Court, your written direct testimony. You swore an oath to tell the truth, right?

A. Yeah. It says here: It was my understanding that ProSupplier could acquire only three bottles, and that was my understanding.

Q. I thought you just told me that you can't tell whether it's accurate or not. Is that statement accurate, that that was in fact your understanding, that ProSupplier could acquire only three bottles?

A. Yes. I can tell you at that time my understanding was that ProSupplier can only supply three bottles.

Q. Did someone tell you that?

A. Not that I recall, no.

Q. Did someone tell anybody at Dr. Reddy's that?

A. I think there was some discussions between me and Dr. Reddy's about how many bottles can we order and how many bottles can we purchase. And it just -- my understanding is that, you know, three bottles is something that we would be able to purchase.

Q. But nobody told you that?

A. No.

Q. No, meaning nobody told you that?

A. I don't remember exactly if somebody said to me were the three bottles the only thing that we can purchase, but my understanding was that it was the right thing to only order three bottles.

MR. CASEY: Could we go to GX-3017, please.

Q. Mr. Shah, you see on the screen GX-3017. Do you see that?

A. Yes.

Q. Is this the letter that you signed on behalf of Cerovene to the FDA?

A. Yes.

Q. On July 13, 2018.

A. Yes.

Q. This is the letter in which you are seeking the waiver, correct?

A. Yes.

Q. The third paragraph, where it starts the test product, you say: Due to the inaccessibility of the RLD, the pharmacy with

which Cerovene is currently dealing is trying to procure Daraprim tablets, is only able to purchase three bottles, 100 count, of the RLD to meet five times retention quantity requirement. We need five bottles, 100 count. The pharmacy has informed that it is not possible to purchase five bottles but can try to procure three bottles and thus will not meet the agency's sample retention requirement of five times the quantity used in finished product testing.

Do you see that?

A. Yes.

Q. You represented to the FDA that the pharmacy that you were dealing with told you it could only get up to three bottles. Is that what you are telling the FDA here?

A. Yes.

Q. What's the pharmacy you are referring to here?

A. Can I look at the date again, if you don't mind?

Q. The date of what, sir?

A. The date of the letter.

Q. Yes.

A. So, yes. I think most likely we were referring to Reliant Pharmacy here.

Q. Did someone from Reliant Pharmacy tell you that it could only acquire three bottles?

A. Yes. That, I think -- the basis of this letter was that, yes, we could only get three bottles.

Q. But your written direct testimony was referring to ProSupplier being the one who led you to understand that they could only acquire three bottles, not Reliant, correct?

A. Yes.

Q. So was it your understanding that both Reliant and ProSupplier had a three-bottle limit?

A. I think the question is very difficult to answer. When we write a letter to FDA, we write the letter based on the information available at that time and to let FDA know what our difficulties are. At the same time, dealing with different suppliers, trying to get the bottles, it's a real time thing.

The letter is written on July 13. I believe that Reliant was not able to provide the bottles, and there were some talks that they can only get three bottles and that's what I wrote here.

Q. Is this statement accurate? He has represented to the FDA that the pharmacy has informed that it is not possible to purchase five bottles. Is that accurate?

A. Yes.

Q. Then you go on: But can try to procure three bottles. Is that accurate too?

A. Yes.

Q. So that's what Reliant told you, correct?

A. That's what I recall, yes.

MR. CASEY: Could we pull up DX-168, please.

Q. Mr. Shah, I'm showing you DX-168, which is an e-mail. Do you recognize that? It's dated September 19 of 2018.

A. Yes.

Q. This is from a Mallikarjuna Reddy. Is that an employee of Dr. Reddy's?

A. Yes.

Q. The e-mail is to you and a number of other individuals. Are they all Dr. Reddy's' employees?

A. Yes.

Q. The subject is Daraprim RLD. It says: Dear all.

THE COURT: Excuse me. Is this in evidence?

MR. MEIER: I believe it is, your Honor. If not, I'll offer it. The defense will offer it DX-168.

MR. WEINGARTEN: No objection, your Honor.

THE COURT: Received.

(Defendant's Exhibit 168 received in evidence)

Q. Mr. Shah, it says: As per our my discussion with Manish on 17-September, we have agreed to go ahead and place order for three bottles with new vendor, ProSupplier, considering below.

Do you see that?

A. Yes.

Q. Manish is you, correct?

A. Yes.

Q. You had a discussion on September 17 with Mr. Reddy and you decided to place an order for three bottles with ProSupplier

with the bullets below being part of that discussion, correct?

A. Yes.

Q. So the first one says: We will insist ProSupplier to supply two bottles from lot number AF6966G, as we already have one bottle from this lot. In case if they are not able to source this lot, we will proceed to buy three bottles from new lot.

What is your understanding of what that bullet is referencing?

A. That seems to be we had one bottle of the same lot. If we get additional two bottles, then we will have three bottles of the same lot. Because you need the same lot to do the bioequivalence study.

Q. At this point, Mr. Shah, September 19 of 2018, your waiver request at the FDA had not yet been granted, correct?

A. No.

Q. No, meaning it had not been granted?

A. The FDA did not grant the request.

Q. That was April of 2019?

A. Correct.

Q. Now, the second bullet says: DRL team will negotiate with ProSupplier to agree for 50 percent advance payment against the order and balance 50 percent when the product is shipped. PO to be placed accordingly.

You see that?

A. Yes.
Q. Does that mean that there is going to be half up front and then half later payment for the RLD?
A. Yeah.
Q. Then it says: We will insist both the vendors, i.e., Reliant and ProSupplier, to promptly inform us ahead of time when they get firm visibility to get the product shipped from their primary source so that we don't end up having product from both the suppliers. We will keep a track on this.

Do you see that?

A. Yes.
Q. What is your understanding of what that means?
A. My understanding is exactly what it reads. There are two vendors and we will keep track of them.
Q. Then it goes on to say: When one supplier is able to deliver the product, we will take refund from the other. This way, we increase chances of having product soon. Correct?
A. Yes.
Q. Now, this plan that you and Mr. Reddy developed was to order a limited number of bottles so that you could get your money back. Isn't that what happened?
A. You can say that, yeah.
Q. So you and Mr. Reddy decided that you weren't going to buy any more than three bottles, correct?
A. I don't exactly see that in this e-mail or I don't recall

having a discussion that we should not buy more than three bottles.

Q. That's not something you discussed with Mr. Reddy?

A. No. The discussion about -- with Mr. Reddy is exactly what it says. Let's try to get the brand bottles, as many as we can, as fast as we can.

Q. But the first line, sir, says: We will insist ProSupplier to supply two bottles, as we already have one bottle. So weren't you agreeing not to buy any more than three bottles?

A. What that says here is that we have one bottle from that lot. And if you get two more bottles, then we will have three bottles. We wanted to use the bottle from that particular lot that the line supplied us.

Q. You wanted to make sure that you didn't end up having product from both the suppliers, correct?

A. Yeah. Because one of the suppliers is asking for the prepayment.

Q. Now, the delivery of the three bottles was on or about November 19 of 2018, correct?

A. Correct.

MR. CASEY: So if we could look at GX-3390, please.

Q. 3390, Mr. Shah, is another e-mail chain. Again, it's from Mr. Reddy at the top. It's to a number of people. You were on this e-mail chain somewhere, correct?

A. Yes.

THE COURT: Excuse me, counsel. Is this in evidence?

MR. CASEY: It is not, your Honor. Thank you. The defense offers GX-3390.

MR. WEINGARTEN: Sorry, your Honor. I don't mean to interrupt, but the last question was: You were on this e-mail chain somewhere, correct? And I am not sure I see where Mr. Shah is on the e-mail chain.

MR. CASEY: Can we go down to page 7, please. I'm sorry. Go up. Keep going up, please. Further up. Further. You can go to page 2, please. I'm sorry, your Honor. I thought Mr. Shah was on this. I withdraw it.

THE COURT: That's all right.

Q. Do you recall that the delivery of the three bottles was on or about November 16, 2018?

A. Yes.

Q. Do you recall that that was within about a month from the initial payment from Dr. Reddy's?

A. I don't recall the exact time frame, but, yes, it could be around that time frame.

Q. But Cerovene did not immediately start its bioequivalency testing after getting the bottles, correct?

A. No.

Q. Sorry. Is the answer, no, you did not start the bioequivalency testing?

A. You said immediately. We didn't start like next day the

bioequivalency study. It took us a while to start the bioequivalency study because CRO is located outside the country.

Q. What is your CRO?

A. Clinical research organization.

Q. Didn't you wait, Mr. Shah, until the FDA had acted on your waiver request to start the bioequivalence testing?

A. I think you can say that because we were waiting for the confirmation for the retention quality requirement.

Q. The FDA approved your waiver request, correct?

A. Yes.

Q. That was in April of 2019, correct?

A. Yes.

Q. You didn't start the bioequivalency testing until May of 2019, correct?

A. Yes.

Q. Just to summarize, in terms of the timeline, the FDA response allowing Cerovene to proceed with the bioequivalence testing using 300 tablets came almost ten months after Cerovene submitted its initial request for reduction in the retention requirements in July 2018, correct?

A. Yes.

Q. And the response came six months after Cerovene had obtained the 300 bottles it needed to conduct the new bioequivalence testing, correct?

A. Yes.

THE COURT: The three bottles. You said 300 bottles. You meant 300 tablets.

MR. CASEY: I misspoke. Let me do that again. I'll try to that again.

Q. The response came six months after Cerovene had obtained the three bottles it needed to conduct the new bioequivalence testing, correct?

A. Yes.

Q. At that point, in April 2019, 16 months had passed since the FDA first notified Cerovene that new bioequivalence testing would be required in December 2017, correct?

A. Yes.

Q. And it was not until May of 2019 that Cerovene actually began its new testing, which was 17 months after the FDA had required the new testing, correct?

A. Yes.

Q. I am going to shift topics, Mr. Shah.

You talked in your written direct testimony about a data source called IQVIA. Do you remember that testimony, paragraph 71 of your direct testimony?

A. Yes.

MR. CASEY: Can we put up the written direct.

Q. You see in paragraph 71 here it says: Cerovene uses IQVIA data in assessing market opportunities. I understand that

IQVIA is the new name for a company formerly known as IMS which provides data about brand-name drug sales. I have used IMS/IQVIA data in my work at Cerovene. I use IMS/IQVIA sales figures for a brand name product as part of deciding whether to invest time and money in developing a generic version of that product.

That's your testimony, correct?

A. Yes.

Q. Now, Cerovene does not subscribe to sales data provided by IMS or IQVIA, correct?

A. We do not subscribe.

Q. So to the extent that you reviewed sales data for Daraprim before beginning work on your ANDA in 2013, is it fair to say that you relied on publicly available information rather than data from a proprietary database?

A. Yes.

Q. After 2013, you made no attempt to obtain IQVIA or IMS sales data for the brand Daraprim, correct?

A. Correct.

Q. Mr. Shah, thank you. That's all the questions I have for you?

THE COURT: Let's take our mid morning recess, everyone.

Give me just one second here. Thanks so much.

(Recess)

MR. WEINGARTEN: Thank you, your Honor. James Weingarten, with the Federal Trade Commission, on behalf of the plaintiffs.

REDIRECT EXAMINATION

BY MR. WEINGARTEN:

Q. Good morning, Mr. Shah.

A. Good morning.

Q. I'm going to ask you some questions about the topics that Mr. Casey talked to you about earlier today. Okay?

A. Okay.

Q. Mr. Casey asked you some questions about RL Fine.

Do you recall that?

A. Yes.

Q. He asked you some questions about the word "free riding."

Do you remember that?

A. Yes.

Q. As part of working with RL Fine, did Cerovene invest time and money in helping RL Fine qualify its pyrimethamine API for use in the United States?

A. Yes.

Q. Could you please explain?

A. Well, typically, we refer DMF in our ANDA when we buy the API substance from any company. But, in this case, RL Fine did not have and did not file the DMF with the U.S. FDA. And that's one of the requirement, to actually get the product

approved with the FDA.

So --

Q. Let me just stop you one second, sir.

DMF stands for drug master file?

A. Drug master file.

Q. Okay. Thank you.

Please continue.

A. Yes.

So -- and they said that, look, if you -- we have no interest in selling this product in USA, for whatever reasons that they had, so we had to then work with them and sort of pay -- and do all of the work, spend money and time, and also pay the FDA fees in order for us to use the API. So all this time and effort was put in by Cerovene and not RL Fine. And we just want to make sure that, you know, nobody will be able to use that material because they have not really put any time. It's us putting all the time and money, and that's what we did.

Q. Mr. Casey asked you if RL Fine had always provided API pyrimethamine API upon request.

Do you remember those questions?

A. Yes.

Q. Now, were you able to use all of the API that RL Fine supplied in making finished sellable product of a generic Daraprim?

Let me ask it this way: Did some of the API that

RL Fine supplied expire?

A. Yes.

Q. And are you allowed to use, under FDA regulations, expired API in finished drug product for sale in the United States?

MR. CASEY: Your Honor, I object. He's leading the witness.

THE COURT: Sustained.

BY MR. WEINGARTEN:

Q. Did there come a point whereby you were able to use the RL Fine API to manufacture sellable product?

A. I'm sorry, can you repeat the question?

Q. Were you able to use all the RL Fine API to make sellable Daraprim product?

A. No.

Q. Did there come a point in time, during your work with RL Fine, where RL Fine declined to continue supporting Cerovene's generic Daraprim product?

A. Yes.

Q. And was it your understanding, after that point in time, that RL Fine would sell you more API or would not sell you more API?

A. I guess you have to rephrase the question.

Q. Okay. Did you travel to India to talk to RL Fine?

A. Yes.

Q. After you met with RL Fine in India, what was your

understanding of whether RL Fine would supply you, or not supply you, with pyrimethamine?

A. So, just to clarify, I traveled to India, I believe, in 2017. At that point, RL Fine said that we would not be able to support anything for the U.S. market. But then, again, I went back in 2020, if I remember correctly, and they said, okay, no problem, we can supply you the API now.

Q. So between 2017, when you met with them, and 2020, what was your understanding about whether RL Fine could supply API, or would supply API, to Cerovene?

A. Based on what they told me, they would not be able to supply me.

Q. Mr. Casey asked you some questions about the relationship between bioequivalence testing requirements and the number of bottles of Daraprim RLD you would need.

Do you remember that?

A. Yes.

Q. When did Cerovene engage Reliant to purchase -- first engage Reliant to purchase Daraprim RLD?

A. February 2018.

Q. And how much RLD did you engage Reliant to procure?

A. Five bottles.

Q. If Reliant had delivered five bottles, would Cerovene have accepted them?

A. Yes.

Q. And would you have used them to make the tests to meet the bioequivalence requirements of the FDA?

A. Yes.

Q. If ProSupplier had said it was able to deliver five bottles, would you have accepted five bottles of Daraprim from ProSupplier?

A. Yes.

Q. Now, Mr. Casey asked you a question about ProSupplier versus Reliant, and he looked at a document with you, Government Exhibit 3395.

MR. WEINGARTEN: Could we please look at Government Exhibit 3395, Ms. Guy. Could you please turn to page 002.

THE COURT: Is this in evidence, counsel?

MR. WEINGARTEN: Your Honor, I'm not sure if Mr. Casey moved it into evidence, but I will do so now, your Honor.

THE COURT: Any objection?

MR. CASEY: No objection, your Honor.

THE COURT: Received.

MR. WEINGARTEN: Thank you.

(Government's Exhibit 3395 received in evidence)

BY MR. WEINGARTEN:

Q. Let's look at 002.

Mr. Casey asked you about the bottom email — it's from Mr. Mukhopadhyay, and it's dated 20 February 2018.

Do you see that?

A. Yes.
Q. I believe he pointed you to the sentences that say, "As we still do not have the RLD from Espee after more than a month, I think we should cancel the PO and work with ProSupplier."
Do you see that?
A. Yes.
Q. What is Espee?
A. Espee is another specialty pharmacy like Reliant or ProSupplier.
Q. Did Cerovene try to get Daraprim RLD from Espee?
A. Yes.
Q. How much?
A. Five bottles.
Q. The next paragraph down, Mr. Mukhopadhyay wrote to you and others, "Ramesh, Malli, can we work with ProSupplier and order for Cerovene?"
Do you see that?
A. Yes.
Q. I want to take you to the top of this.
MR. WEINGARTEN: Back to page 001, please. Let's look what happens at the rest of this email chain. If you could start with that email at the bottom, February 20, 2018, at 11:27 p.m.
Q. This one is also from a Mr. Reddy, who works at Dr. Reddy's, correct?

A. Yes.

Q. And Mr. Reddy writes, in the first paragraph, "We checked again with ProSupplier, and they have indicated four to six weeks' lead time after providing PO and prepayment. We have also checked with other vendors, and Reliant is now ready to supply the same within two weeks after receipt of PO and prepayment."

Do you see that, sir?

A. Yes.

Q. What is the difference, from your perspective, in developing the drug between four to six weeks' lead time and two weeks' lead time?

A. Well, it's a big difference, right, because we could start the bioequivalence study that much earlier.

Q. If we go to the top email, page 001, this is from Mr. Mukhopadhyay, who had written the email earlier about working with ProSupplier, and it's dated February 21st, and the second paragraph of the email says, "Manish, seems all pharmacies are requesting prepayment." Let's stop there.

What does it mean, "requesting prepayment"? Do you understand that?

A. Yes. It means they need advance payment before they can supply the bottle.

Q. Could you please speak a little slower, sir?

A. They need an advance payment before they can actually

supply the bottle.

Q. And Mr. Mukhopadhyay writes, "My suggestion would be for Cerovene to wire transfer the funds to DRL, and we can place the order with Reliant based on the PO below and prepayment."

Did Cerovene ultimately decide, at this point, to continue moving forward with Reliant and not ProSupplier?

MR. CASEY: Objection; leading.

THE COURT: Overruled.

THE WITNESS: Yes.

BY MR. WEINGARTEN:

Q. Why?

A. For the reasons that it is possible to get in two weeks versus four to six weeks.

Q. And Mr. Mukhopadhyay writes, at the end there, "We need to move quickly, as we have already been delayed by two months since the CR."

What is "CR," sir?

A. It's a complete response.

Q. And what is a complete response?

A. It's basically FDA's consent, their complete response letter in 2017, saying that we could not approve the Cerovene's ANDA.

Q. And at this time, did you agree with Mr. Mukhopadhyay about the need to move quickly?

A. Yes.

Q. Why did you want to move quickly?
A. So we could finish the bioequivalency study and get approval of the product.
Q. Thank you.
MR. WEINGARTEN: You can take that document down now, Ms. Guy.
Q. Now, Mr. Casey asked you several questions about three bottles versus five bottles.
Do you remember that?
A. Yes.
Q. Now, I don't want you to say the name of the pharmacy, but was there a pharmacy that in the past you had ordered Daraprim bottles from that had delivered them?
A. Yes.
Q. Did you try to order bottles from that pharmacy again after the FDA told you Cerovene would need to do new bioequivalence testing?
A. Yes.
Q. And how soon after the FDA letter telling you that did you contact that pharmacy?
A. If I recall, probably the next day.
Q. And based on your prior experience seeking Daraprim from that pharmacy, how long did you think it would take to source five bottles of Daraprim?
A. Probably one or two days.

Q. And was that pharmacy able to supply Daraprim to you?
A. No.
Q. If you could have gotten five bottles from that local pharmacy, would you have accepted them?
A. Yes.
Q. And would you have used them to meet the FDA bioequivalency requirement?
A. Yes.
Q. At this point in time, if an RLD supplier had offered to deliver five bottles of Daraprim RLD, would you have accepted five bottles of Daraprim RLD?
A. Yes.
Q. Let's look, please, at Defense Exhibit 168. This is also a document that Mr. Casey showed you.

Do you remember Mr. Casey asking you some questions about Defense Exhibit 168?
A. Yes.
Q. And this is an email from a Mr. Reddy, who works at Dr. Reddy's, correct?
A. Yes.
Q. And it's dated September 19, 2018, correct?
A. Yes.
Q. And you are one of the recipients?
A. Yes.

MR. WEINGARTEN: And I'm not sure if it was moved into

evidence, your Honor, but at this time --

THE COURT: It is.

MR. WEINGARTEN: It is? Okay. Thank you.

BY MR. WEINGARTEN:

Q. And Mr. Casey went over some of these bullets with you, correct?

A. Yes.

Q. I want to ask you to help clear up something about the first bullet.

Now, in the first bullet, it says, "We will insist ProSupplier to supply two bottles from a lot number" -- it gives the number — "as we already have one bottle from this lot."

Now, I think you got this briefly with Mr. Casey, but I want to make sure it's understood: Why does it matter if the bottles are from the same lot or not?

A. Because that's one of the requirement of FDA, to conduct the biostudy from the same lot of RLD.

Q. If you could have gotten bottles from the same lot from only one supplier, would you have done that?

A. Yes.

Q. And if you had to use a combination of suppliers to get enough bottles to meet FDA requirements, would you have tried that?

A. Yes.

Q. Now, Mr. Casey asked you a question about you receiving the bottles from ProSupplier in November 2018.

Do you remember those questions?

A. Yes.

Q. In November 2018, you got three bottles -- sorry. How many bottles did ProSupplier deliver?

A. Three bottles.

Q. And Mr. Casey asked you some questions about waiting to start bioequivalence testing.

Do you remember that?

A. Yes.

Q. In November 2018, when you got the three bottles from ProSupplier, had FDA approved the use of only three bottles for your bioequivalence testing?

A. No.

Q. When you started the bioequivalence testing, did you do so after the FDA had approved the use of three bottles for bioequivalence testing?

A. Yes.

Q. Throughout this development process, sir, what was your goal in reaching the marketplace with a Daraprim generic product?

A. The goal was to get approval as fast as possible and commercialize the product.

MR. WEINGARTEN: Nothing further at this time, your

Honor.

THE COURT: Any recross?

MR. CASEY: No, recross, your Honor. Thank you.

THE COURT: Thank you so much.

So, Mr. Shah, if I could direct your attention to page 7 of your direct testimony. It's my understanding, from your discussion on page 7 of your interactions with Fukuzyu, that it was your desire, your preference, to use Fukuzyu API.

Am I right?

THE WITNESS: Yes.

THE COURT: If Fukuzyu had agreed to supply you with its API, would you have, instead, chosen to proceed with RL Fine?

THE WITNESS: No.

THE COURT: So I want to have you discuss for me something that did not occur. Let us assume that Fukuzyu had agreed to supply you with their API in the fall of 2016.

THE WITNESS: Okay.

THE COURT: I'd like you to also assume a second thing — that when you went into the marketplace to get Daraprim, the RLD, if you needed more Daraprim, you would have had no difficulty getting it; for instance, you could go back to that same pharmacy we are not naming and get as many bottles as you wanted. Okay? That's the second assumption.

THE WITNESS: Okay.

THE COURT: So could you walk me through the steps you would have needed to take with those two assumptions and help me create a timeline for how long it would have taken you then, you expect, based on your experience, to actually enter the marketplace, to get FDA approval and to enter the marketplace?

THE WITNESS: Okay, okay.

So if we have gotten the Fukuzyu API and --

THE COURT: When? What date?

THE WITNESS: Let's say October 2016.

And if there was no issue getting the RLD Daraprim, then we would make one batch, which we call a registration batch --

THE COURT: Which you call a what special batch?

THE WITNESS: A registration batch.

THE COURT: A registration batch?

THE WITNESS: Registration batch.

We would make one batch, and then we had to wait for three months of stability data. Within that three months, if I had the RLD, then I could have done the study, also. So from my perspective, we would require four months to get the stability data done, to produce one batch, and get the bio study done, and then we could file the amendment. If it's not, file an amendment with FDA saying that we want to change the API source from Ipca source to Fukuzyu source.

THE COURT: So let me stop you there.

So before you could amend your ANDA, you believed you would need to take the following steps — you would need to make a registration batch?

THE WITNESS: Correct.

THE COURT: You would need to wait three months to obtain stability data?

THE WITNESS: Correct.

THE COURT: After you make the batch?

THE WITNESS: Yes.

THE COURT: So that's four months?

THE WITNESS: Yes.

THE COURT: And during that four-month period, you would do, at the same time, the bioequivalency testing?

THE WITNESS: Yes.

THE COURT: So you would say it would take you four months from the October 2016 to the filing of your amended ANDA?

THE WITNESS: Correct.

THE COURT: So we're just going to say, roughly, February of 2017?

THE WITNESS: Yes.

THE COURT: Next step?

THE WITNESS: And once you file the amendment, then it's really up to the FDA how quickly they would approve the ANDA, right? So that timeline is something really up to FDA,

but FDA generally gives you a goal date. Whenever you do the file date, FDA generally give you goal date, and those goal dates, depending upon what the amendment is — in this case, it would be a major amendment — I would say about six to nine months. It could be three months, six months, but most likely six months.

THE COURT: Given the fact that you would have been using, under this hypothetical, Fukuzyu's API, would you have been optimistic that you would have been approved at the end of that six-month period?

THE WITNESS: Yes. So, two reasons for yes:

One is we believe that Fukuzyu is the API that's been used in the RLD Daraprim. So I don't believe FDA would have a major deficiency as it relates to the API. And if our bioequivalency studies successfully passed, then there's no reason for FDA not to give the approval.

THE COURT: So let us say that the FDA gives you approval. How long, then, to get the product into the market?

THE WITNESS: I would say we could be in the market in less than three months.

THE COURT: And what is taking you three months to do? What's happening in that interval?

THE WITNESS: So as to the FDA's guidance, you have to produce three batches, which we call process validating batches, and we have to validate -- so produce three batches,

then you have to do what we call process validation testings. And once we finish up those testings, then we have to prepare a complete report on those three batches, which is lot more testing than you would normally do for a commercial batch.

So any batch you make after that three batches would be a true commercial batch, and we would then require reduced testing, so it doesn't take that much time to release that batch. But for the first three batches, we have to do lot more testing.

So we -- I suppose we can move faster, we can try to do it within, let's say, one and a half months, but it would not take us more than three months to produce -- to commercially launch the product.

THE COURT: So after you create the three batches and do that intense testing regimen and then create more batches for the market, are you reporting to the FDA? You said you use these tests to create a report.

THE WITNESS: So that particular report is not submitted to FDA, but you are expected to provide that report when FDA comes for a full inspection because the first thing they would ask is, we need your process validation report. And if you don't have it, then it's sort of a violation of FDA.

THE COURT: So let me just make sure I have this timeline correct. So you file your amendment in February, you think it's likely the FDA would have taken six months to render

its decision, you think it's very likely that would have been an approval?

THE WITNESS: Yes.

THE COURT: It could have taken the FDA as long as nine months, but you think six months is more likely?

THE WITNESS: Yes.

THE COURT: So that is August of 2017, and then you need three more months after approval in order to validate your process through testing of additional batches?

THE WITNESS: Yes.

THE COURT: So that's November of 2017 to enter the market?

THE WITNESS: Yes.

THE COURT: Now, I suppose you could have done this testing of the process, the creation of the three batches and the testing and the validation, while you were waiting for the FDA to react to your ANDA?

THE WITNESS: Certainly, yes.

THE COURT: And maybe other pharmaceutical companies would choose to do that?

THE WITNESS: Yes.

THE COURT: I've heard reference to something called CGT status.

Are you familiar with that term?

THE WITNESS: Yes.

THE COURT: What is your understanding of that term?

THE WITNESS: So it's an FDA -- with the new GDUFA regulations, FDA's come up with an incentive situation for generic drugs, where if you are the first generic that is either getting approved or first generic being filed, then FDA gives you some incentive with an expeditious review.

THE COURT: And that's only for the first generic?

THE WITNESS: Yes.

THE COURT: Excuse me one minute, counsel.

(Pause)

THE COURT: Counsel, do you have additional questions for this witness, given the questions I have put to him?

MR. WEINGARTEN: Just a few very, very briefly, if it's okay, your Honor.

REDIRECT EXAMINATION

BY MR. WEINGARTEN:

Q. Judge Cote asked you some questions about a hypothetical world. I just want to ask you, very briefly, about the real world.

Do you remember, in the real world, the date the FDA approved Cerovene's generic Daraprim product?

A. Say that again?

Q. Do you remember, in the real world that actually happened, the date the FDA approved Cerovene's generic Daraprim product?

A. Yes. And that was February 28, 2020.

Q. Okay. February 28, 2020.

And in the real world, do you remember what date the product launched in the marketplace?

A. We believe we launched directly in March 2020.

Q. So in the real world, it only took one month from approval to launch?

A. Yes.

Q. Okay.

MR. WEINGARTEN: Nothing further, your Honor. Thank you.

THE COURT: Any additional questions?

MR. CASEY: No, your Honor. Thank you.

MR. WEINGARTEN: Briefly, your Honor, we have another GX 9000 number that relates to this witness that I could move into evidence.

THE COURT: Sure. Should he be on the stand for that just in case?

MR. WEINGARTEN: Sure, if there's any objection. I don't think there are.

If I may approach, your Honor. This is GX 9011, and the government moves to admit GX 9011 and the exhibits therein.

THE COURT: Any objection?

MR. CASEY: No objection.

THE COURT: Received.

(Government's Exhibit 9011 with the exhibits within

received in evidence)

MR. WEINGARTEN: Thank you.

THE COURT: You may step down.

THE WITNESS: Thank you.

(Witness excused)

THE COURT: Next witness.

MR. MEIER: Your Honor, the government calls, as its next witness, Nilesh Patel, N-i-l-e-s-h and Patel is P-a-t-e-l, and my colleague from the New York Attorney General's Office, Elinor Hoffmann, will be the attorney for the government on this one, your Honor.

THE COURT: Sir, if you could come up, take the witness stand, and remain standing.

NILESH PATEL,

called as a witness by the Plaintiffs,

having been duly sworn, testified as follows:

THE COURT: You're about to be given a document which is -- I'm sorry, please state your full name and spell your first and last name for the record.

THE WITNESS: Nilesh Patel, N-i-l-e-s-h P-a-t-e-l.

THE COURT: Thank you.

And, Mr. Patel, if you could move your chair closer.

Thank you.

Our ventilation system in this room has been tested, so if you wish, you may remove your mask, and you may move that

microphone in a way that keeps it low, a little under your chin, but speak directly into it.

THE WITNESS: Okay.

THE COURT: Thank you.

I believe you're about to be handed a document which is marked as GX 8010. I'm going to ask you to look at page 14.

And I'm going to ask if that is your signature on page 14 of that exhibit?

THE WITNESS: Yes.

THE COURT: Before signing that document, did you read it with care?

THE WITNESS: Yes.

THE COURT: Do you swear to the truth of its contents?

THE WITNESS: Yes.

THE COURT: Any objections to receipt of GX 8010?

THE WITNESS: No.

MS. STEWART: Sarah Stewart, your Honor.

No objection.

THE COURT: It is received.

(Government's Exhibit 8010 received in evidence)

THE COURT: Cross-examination.

MS. HOFFMANN: Your Honor, I have a few exhibits, which I thought we might introduce at the beginning, or would you --

THE COURT: Certainly. That's fine.

MS. HOFFMANN: This is GX 9012, and these are documents that were attached to the affidavit. They're listed on this exhibit. I don't believe there are any objections.

THE COURT: Any objections to the receipt of GX 9012 and the exhibits listed on it?

MS. STEWART: Sarah Stewart, your Honor.

No objections.

THE COURT: Received.

(Government's Exhibit 9012 and exhibits within received in evidence)

THE COURT: Cross-examination?

CROSS-EXAMINATION

BY MS. STEWART:

Q. Good morning, Mr. Patel. My name is Sarah Stewart, here for Defendant, Martin Shkreli. I have a few questions for you this morning.

In 2014, InvaTech decided to begin developing a generic version of Daraprim, correct?

A. Yes.

Q. And in 2014, InvaTech's efforts to develop a generic Daraprim product began with reviewing IMS sales data for Daraprim; is that correct?

A. Yes.

Q. InvaTech received the IMS sales data from one of its marketing partners, a company called Trident Laboratories,

correct?
A. Yes.
Q. And since receiving the sales data in 2014, InvaTech hasn't asked for any other sales data related to Daraprim, correct?
A. Yes.
Q. Now, part of InvaTech's efforts to develop a generic Daraprim product, that included bioequivalence testing, correct?
A. Yes.
Q. And to conduct bioequivalence testing, InvaTech needed to obtain tablets of the branded drug, correct?
A. Yes.
Q. InvaTech needed three 100-tablet bottles of Daraprim, correct?
A. Yes.
Q. InvaTech, in fact, obtained tablets of Daraprim, correct?
A. Yes.
Q. InvaTech obtained 600 tablets of Daraprim, correct?
A. Yes.
Q. And InvaTech obtained these 600 tablets in October of 2014, correct?
A. Yes.
Q. So as of October 2014, InvaTech had the Daraprim samples that it needed to conduct bioequivalence testing, correct?
A. Yes.

Q. InvaTech did not purchase any Daraprim after 2014, correct?
A. Yes.
Q. And InvaTech did not attempt to purchase any Daraprim after 2014, correct?
A. Yes.
Q. And InvaTech, in fact, used the Daraprim that it obtained in 2014 to conduct bioequivalence testing, correct?
A. Yes.
Q. Let's change topics to InvaTech's pyrimethamine suppliers.

The first supplier with which InvaTech contracted was Ipca Laboratories, correct?
A. Yes.
Q. And you identified Ipca by reviewing Ipca's website; is that correct?
A. Yes.
Q. Did you also identify Ipca by reviewing the drug master file, or DMF, list?
A. DMF list.
Q. I'm sorry, I did not hear that.
A. DMF list.
Q. Yes?
A. Yes.
Q. Thereafter, you contacted Ipca by phone, correct?
A. Their local office in New Jersey.
Q. You contacted them at a local office in New York City?

A. New Jersey.
Q. New Jersey by phone?
A. Yes.
Q. And other than speaking with Ipca by phone and reviewing the website and the DMF list, InvaTech did not do any other research in connection with selecting Ipca, correct?
A. No.
Q. Correct, no other research was done?
A. That is correct.
Q. Okay. Thank you.

InvaTech did not do a site visit of Ipca's manufacturing facilities, correct?
A. No.
Q. Correct, that they did not visit the manufacturing facilities?
A. I never visited Ipca's facility.
Q. Thank you.

And InvaTech did not meet with anyone from Ipca in person, correct?
A. Local agent, yes.
Q. You met with a local agent?
A. Yes.
Q. But no one at the manufacturing facility?
A. No.
Q. At the time InvaTech contracted with Ipca, it did not look

for or consider any other API suppliers, correct?
A. Yes.
Q. Ipca supplied pyrimethamine to InvaTech in 2014, correct?
A. Yes.
Q. Now, the FDA imposed an import ban on Ipca in 2015, correct?
A. Yes.
Q. And that import ban on Ipca, it delayed InvaTech's development of a generic Daraprim product, correct?
A. Yes.
Q. That's because InvaTech had to find a new supplier, correct?
A. Yes.
Q. Now, in summer of 2015, you learned of RL Fine and that it was a potential supplier of pyrimethamine, correct?
A. Yes.
Q. And you contacted RL Fine by phone; is that correct?
A. Yes.
Q. And then you met RL Fine at a pharmaceutical industry conference, DCAT, in New York City; is that correct?
A. Yes.
Q. And at that conference, you discussed with RL Fine the potential of supplying pyrimethamine to InvaTech, correct?
A. Yes.
Q. And InvaTech understood, from those discussions with

RL Fine, that RL Fine was supplying pyrimethamine outside the United States, correct?

A. Yes.

Q. And InvaTech chose RL Fine as its new pyrimethamine supplier because it was already supplying outside of the United States, correct?

A. Yes.

Q. Before choosing RL Fine, InvaTech didn't conduct a supplier's audit of RL Fine, did it?

A. Can you repeat?

Q. Before choosing RL Fine, InvaTech did not conduct a supplier's audit of RL Fine, correct?

A. No.

Q. Correct as in no, no audit was conducted?

A. No audit was conducted.

Q. Okay. Thank you.

And at this time, when InvaTech decided to work with RL Fine, InvaTech did not research whether there were other companies supplying pyrimethamine outside the United States, correct?

A. Yes.

Q. Now, when you first contacted RL Fine, it did not have a DMF for pyrimethamine, correct?

A. Yes.

Q. But InvaTech did not take any steps to have RL Fine file a

DMF for pyrimethamine in the summer of 2015, correct?
A. Yes.
Q. But, as far as you knew, RL Fine could have filed a DMF in the summer of 2015, correct?
A. They were not ready.
Q. I'm sorry, could you say that --
A. They were not ready at that time to file.
Q. But, as far as you knew, nothing was preventing RL Fine from filing the DMF?
A. Yes.
Q. And RL Fine first sent pyrimethamine to InvaTech in September of 2015, correct?
A. Yes.
Q. Let's fast forward to November of 2016. RL Fine still hadn't filed the DMF, correct?
A. Yes.
Q. So RL Fine was delaying in filing the DMF, correct?
A. Yes.
Q. Now, InvaTech and RL Fine entered into a written agreement, correct?
A. Yes.
Q. And the agreement required RL Fine to provide a pyrimethamine DMF, correct?
A. Yes.
Q. The agreement also contemplated submission of an ANDA for

InvaTech's pyrimethamine product in 2017 or 2018, correct?

A. Yes.

Q. And InvaTech was ready to submit its ANDA for generic Daraprim in January of 2017, correct?

A. Yes.

Q. But RL Fine had not provided the DMF by that time, correct?

A. Yes.

Q. And let's fast forward again approximately six months, to June of 2017, and RL Fine had still not provided the DMF, correct?

A. Yes.

Q. InvaTech ultimately decided to submit its ANDA despite RL Fine not having provided the DMF, correct?

A. Can you repeat it?

Q. InvaTech decided to submit the ANDA without RL Fine having obtained the DMF, correct?

A. Yes.

Q. And to submit the ANDA, InvaTech actually took it upon itself to include the DMF information within the ANDA, correct?

A. Yes.

Q. And InvaTech decided to do this, submit the DMF information within the ANDA, even though it would have been easier and faster for the FDA's review if there was a separate DMF on file, correct?

A. Yes.

Q. And you did this because RL Fine was taking too long, correct?
A. Yes.
Q. Now, there came a time when RL Fine decided it would no longer support InvaTech's ANDA for generic Daraprim, correct?
A. Can you repeat?
Q. There came a time when RL Fine decided it would no longer support InvaTech's ANDA for the generic Daraprim, correct?
A. Yes.
Q. And this was toward the end of September 2017, correct?
A. Yes.
Q. And in September 2017, you went to RL Fine's headquarters in India, correct?
A. Yes.
Q. And you went there to discuss why RL Fine had decided to no longer support InvaTech's pyrimethamine ANDA, correct?
A. Yes.
Q. And the reason you were given by RL Fine was that pyrimethamine was a small-volume project, correct?
A. Yes.
Q. But InvaTech did not offer to purchase larger volumes of pyrimethamine, correct?
A. Yes.
Q. Are you aware that it was not until three months after this September 2017 meeting that RL Fine entered into a

collaboration and supply agreement with Vyera?

A. No.

Q. You're not aware of that fact?

A. No.

Q. Okay. That's fine.

After RL Fine's decision to no longer support InvaTech's ANDA, InvaTech had to find a new supplier, correct?

A. Yes.

Q. InvaTech started looking for a new supplier in late 2017/early '18?

A. Can you repeat?

Q. InvaTech started to look for a new supplier in late 2017 or the early 2018 time frame, correct?

A. Yes.

Q. And InvaTech found a company that we're going to refer to here as API 2, correct?

A. Yes.

Q. And when I refer to API 2, are you clear who I'm referring to?

A. Yes.

Q. Now, you have a role with API 2, correct?

A. Yes.

Q. And what is that role?

A. I was their U.S. agent for acting with FDA and biopharma for filing their DMFs.

Q. So you're familiar with API 2 as a result of that role?
A. Yes.
Q. And API 2 was the only company that InvaTech looked at and considered after it stopped working with RL Fine, correct?
A. Yes.
Q. And in considering API 2, InvaTech did no due diligence on API 2's ability to supply InvaTech with pyrimethamine, correct?
A. Yes.
Q. And at this time, API 2 did not have a DMF for pyrimethamine, correct?
A. Yes.
Q. API 2 did not even manufacture pyrimethamine, correct?
A. Yes.
Q. And API 2 did not have a process to manufacture pyrimethamine, correct?
A. Yes.
Q. So API 2 had to develop a process to manufacture pyrimethamine, correct?
API 2 had to develop a process to manufacture pyrimethamine, correct?
A. We had given them the documents from our ANDA to produce that.
Q. You provided them documents or instructions to assist them to create a process; is that --
A. No. From our filing, we have provided the section of DMF

to reproduce that API.

Q. So you provided them information, so they could reproduce --

A. Yeah.

Q. -- that process? Okay.

And that took API 2 about six months --

A. Yes.

Q. Okay. Thank you.

Now, in May of 2018, the FDA issued a complete response letter to InvaTech's pyrimethamine ANDA, correct?

A. Yes.

Q. And the letter was a major deficiency response, correct?

A. Yes.

Q. And a major deficiency means there will be extensive additional review, correct?

A. Yes.

Q. Lengthy additional review, correct?

A. Yeah.

Q. And some of the deficiencies had nothing to do with the pyrimethamine API, correct?

A. That is related to a drug product, a few.

Q. But some had nothing to do with the API, correct?

A. Yes.

Q. And InvaTech responded to the major deficiency letter in July of 2019, correct?

A. Yes.
Q. And after that, the FDA sent another reply to InvaTech's letter in January 2017 -- sorry, January 2020, correct?
A. Yes.
Q. And this letter was a minor deficiency response, correct?
A. Yes.
Q. And a minor deficiency means there will be some additional review, correct?
A. Yes.
Q. At least a few more months of review?
A. Yeah.
Q. And some of these deficiencies had nothing to do with the pyrimethamine API, correct?
A. A few, yes.
Q. Just a few, but not all of them?
A. Not all.
Q. Okay.

InvaTech still hasn't responded to the FDA's January 2020 letter, correct?

A. We have responded.
Q. You have responded?
A. Yeah.
Q. You had not responded as of the date you signed your affidavit; is that accurate?
A. Yes.

Q. But you've recently responded?

A. Yes.

Q. And you were delayed in responding because of the COVID pandemic; is that correct?

A. Yes.

Q. And you're still awaiting a response from the FDA, correct?

A. Yes.

MS. STEWART: I have no further questions.

(Continued on next page)

MR. MEIER: Your Honor, while Ms. Hoffmann is coming up, I would like to inform the Court. We have been working very hard to make sure we have witnesses, but this afternoon it does not look like we are going to be able to go until 5:00 this afternoon. It looks like after this witness we only have one more that we have been able to get to court, and I don't think it's going to go for the two hours. I just wanted to let the Court know that before the lunch break.

THE COURT: We will talk about the implications of that because, as know, we have a schedule. We have a day for summations and a day on which evidentiary presentation will conclude, but we can talk about that later. Thank you for the heads-up.

Counsel.

THE WITNESS: Can I make one correction?

THE COURT: Yes, you may.

THE WITNESS: For the last question asked about filing of that answer, that is still pending. Answer to the last query is still pending.

REDIRECT EXAMINATION

BY MS. HOFFMANN:

Q. Good afternoon, Mr. Patel. Thank you for being here today.

Mr. Patel, I am going to be asking you a few questions following up on the questions that you just responded to.

First of all, do you recall Ms. Stewart asked you

about the purchase of some Daraprim RLD back in 2014?
A. Yes.
Q. Do you recall that you told her you purchased or InvaTech purchased six bottles?
A. Yes.
Q. Did you have any difficulty in acquiring those bottles in 2014?
A. No.
Q. Do you recall how much InvaTech paid for those bottles in 2014?
A. Approximately around $1600 per bottle.
Q. For all six bottles?
A. No. All six bottle would be around 8,000 or $9,000.
Q. About $8,000 in 2016 -- in 2014?
A. Yes.
Q. Did you use those Daraprim pills in conducting bioequivalency testing?
A. Yes.
Q. Do you recall when you conducted those bioequivalency tests?
A. Around 2016, '17.
Q. If you had to do bioequivalency testing now, would you be able to do that?
THE COURT: With Daraprim that you purchased in 2014. Is that your question, counsel?

MS. HOFFMANN: Yes. Thank you.

A. That might be expired.

Q. Do you have any access to additional bottles of Daraprim?

A. I haven't worked on that.

Q. Do you recall, switching topics now, Ms. Stewart asked you about your relationship with RL Fine?

A. Um-hum.

Q. At the time you chose RL Fine to be the API supplier, did RL Fine have a DMF on file?

A. No.

Q. Why did you choose RL Fine?

A. Because of their technical capabilities and they held some APIs in the U.S. market, which was commercial.

Q. Do you recall you told Ms. Stewart that they were supplying pyrimethamine in other countries?

A. Yes.

Q. Now, when was the agreement with RL Fine executed?

A. Around 2017.

Q. Does February 2017 sound correct to you?

A. Yes.

Q. When did InvaTech file its ANDA for generic Daraprim?

A. Around July, June July of 2017.

Q. After InvaTech filed, did InvaTech get some initial questions from the FDA?

A. Yes.

Q. Did you request that RL Fine assist you with responding to those initial questions?
A. Yes.
Q. How long after you got those initial questions did you request RL Fine to respond?
A. They requested multiple times.
Q. I am not sure I understood your response. How long did it take you to ask RL Fine to help you respond to those initial questions after you got the questions from the FDA?
A. They never responded.
Q. They never responded. RL Fine never responded.
A. Yes.
Q. Did you ask RL Fine to help you respond right after you got the questions from the FDA?
A. Yes.
Q. As you said, RL Fine never responded to you, is that correct?
A. Yes.
Q. Did you tell RL Fine that those questions were time sensitive?
A. Yes.
Q. And did you ask them to respond as soon as possible?
A. Yes.
Q. Now, I believe you told Ms. Stewart that at some point RL Fine -- you understood that RL Fine was not going to support

InvaTech with Daraprim API, is that correct?
A. Yes.
Q. You told Ms. Stewart that you were given a reason for RL Fine not supporting InvaTech with API, is that correct?
A. Yes.
Q. What was that reason again?
A. Small volume.
Q. Did you find that credible?
A. Not really.
Q. Why not?
A. Initially, we discussed my requirement, and I believe it was spelled out correctly with them, the requirement to be 10 to 15 KG per year for InvaTech.
Q. When you say initially had discussed that requirement, that was at the time you signed the agreement with RL Fine back in February of 2017?
A. Yes.
Q. You were given this reason about nine months later?
A. Yes.
Q. That was on your trip to India?
A. Yes.
Q. Do you recall discussing a complete response letter with Ms. Stewart that InvaTech received from the FDA?
A. Can you repeat it.
Q. Do you recall discussing with Ms. Stewart a complete

response letter that InvaTech received from the FDA?
A. Yes.
Q. Do you remember about when you received that complete response letter?
A. January, February of 2018.
MS. HOFFMANN: Let's look at document 3173.
Q. Do you recognize this document, Mr. Patel?
A. Yes.
THE COURT: Is this in evidence?
MS. HOFFMANN: Yes, it is, your Honor. It is part of Exhibit 9012, I believe.
Q. Mr. Patel, could you turn to the very last page of that document.
MS. HOFFMANN: Rather, Ms. Guy, could you put up the very last page of this document where there is a digital signature.
Q. Mr. Patel, does this refresh your recollection of the date of the complete response --
A. Yes. That is May 2018.
Q. After you got that complete response letter, did you ask RL Fine once again to help you respond to it?
A. Yes.
Q. Did RL Fine give any help to InvaTech in responding to that letter?
A. No.

Q. When did you ask RL Fine to help you respond to the FDA's complete response letter?
A. Immediately after getting this letter.
Q. Did RL Fine ever give you any help in responding to the complete response letter?
A. No.
Q. Switching topics a bit, after you understood that RL Fine was no longer going to support InvaTech, did you look for another API supplier?
A. Yes.
Q. That API supplier was the firm we are calling API 2. Do you remember telling Ms. Stewart that?
A. Yes.
Q. Did API 2 have a DMF for pyrimethamine?
A. No.
Q. Had API 2 ever made pyrimethamine before?
A. No.
Q. Did API 2 have a process or knowhow for making pyrimethamine?
A. No.
Q. Was API 2 a firm that you considered back in 2015?
A. No.
Q. Why did you choose API 2?
A. They helped set up for the small quantity manufacturing and, at the same time, I was working with them as their U.S.

agent in filing DMF on behalf of API 2. So I know that technical capability, their production capability.

Q. I believe you told Ms. Stewart that it took API 2 approximately six months to develop a manufacturing process, is that correct?

A. Yes.

THE COURT: Is this a good time to break for lunch, counsel?

MS. HOFFMANN: Yes. I have about 10 more minutes of questions.

THE COURT: Good. We will break for lunch.

Counsel I have a criminal proceeding during the luncheon recess. I'm afraid we are going to need to use those tables, but we won't need to use all of it. If you could just clear out a section for counsel.

Thank you so much. See you after lunch.

(Recess)

(Continued on next page)

AFTERNOON SESSION

2:00 P.M.

(Trial resumed; in open court)

THE COURT: Please be seated.

The witness may retake the stand.

Just one second, counsel. Let me get set up here.

MS. HOFFMANN: Sure.

THE COURT: Good. I'm ready. Thank you.

MS. HOFFMANN: Thank you.

BY MS. HOFFMANN:

Q. Mr. Patel, if you would like, I think you can remove your mask.

THE COURT: Oh, you don't have to. You don't have to.

BY MS. HOFFMANN:

Q. Mr. Patel, good afternoon, and I want to just get us back to where we were before the lunch break. We were talking about API 2, the supplier to which InvaTech turned after RL Fine withdrew.

You chose API 2 in late 2017 or early '18; is that correct?

A. Yes.

Q. And at the time you chose API 2, they did not have a manufacturing process in place for making pyrimethamine, correct?

A. Yes.

Q. And I think just before we left for lunch, you told me that it would take about six months for API 2 to develop a manufacturing process?
A. Yes.
Q. Did it take six months?
A. Approximately, yes.
Q. And after they developed a manufacturing process, were there additional steps that API 2 had to take before they were in a position to further your regulatory process with the FDA?
A. Yes.
Q. What were those steps?
A. The steps — we had to manufacture additional batches, comparative resolutions, and other testing to have established similarity of the API and file it again.
Q. Did API 2 have to prepare its own certificates of analysis?
A. Yes.
Q. When was API 2 able to give InvaTech the information that InvaTech needed to respond to the FDA's May 2018 complete response letter?
A. Somewhere in 2019.
Q. Does June 2019 sound correct?
A. Yes.
Q. It took about eight months, total, between the time you chose API 2 until the time they were done with the work they needed to do to help you respond?

A. Yes.
Q. When did InvaTech actually respond to the 2018 FDA letter?
A. After receiving all documents and everything, submitted October 2018.
Q. We can look at GX 3168 to refresh your recollection.
Mr. Patel, Ms. Guy has put up GX 3168. Do you recognize -- I realize this document is redacted --
A. Yes.
MS. STEWART: Objection. I don't know that counsel established the failure of recollection.
THE COURT: Oh, I thought she did, but you may inquire again.
BY MS. HOFFMANN:
Q. Mr. Patel, do you recall the date when InvaTech responded to the FDA's 2018 letter?
A. Somewhere in October 2018.
MS. HOFFMANN: And I wanted to put up the document to refresh his recollection because I believe the document has a different date. In any event, this document is in evidence.
Your Honor, may I proceed?
THE COURT: Yes.
BY MS. HOFFMANN:
Q. So, Mr. Patel, do you recognize this document?
A. Yes.
Q. And what is it?

A. That is a response to FDA's correspondence.
Q. And, Mr. Patel, can you turn to page 3 of this document.
Mr. Patel, does that refresh your recollection as to the date of InvaTech's response to the FDA's 2018 letter?
A. It's July 2019, after receiving the letter.
Q. Would InvaTech have been able to respond to the FDA's letter at an earlier date if RL Fine had continued to supply InvaTech?
A. Yes.
MS. STEWART: Objection; leading.
THE COURT: Overruled.
BY MS. HOFFMANN:
Q. Mr. Patel, I just want to --
THE COURT: Well, I'm sorry, I thought that was the introduction to -- that was it for that line?
MS. HOFFMANN: Yes.
THE COURT: Sustained.
BY MS. HOFFMANN:
Q. Mr. Patel, I just want to set some background here about your experience.
Are you one of the cofounders of InvaTech?
A. Yes.
Q. What is InvaTech's business?
A. We are a CDMO company, and we do manufacture products, development of the products, and commercialization of ANDA

products.

Q. Does InvaTech submit abbreviated new drug applications, ANDAs, as part of its business?

A. Yes.

Q. And has InvaTech developed around 50 products?

A. Yes.

Q. And what is your position at InvaTech?

A. Compliance and regulatory officer.

Q. Do you review and supervise InvaTech's correspondence with the FDA?

A. Yes.

Q. And that is just one of your functions there; is that correct?

A. Yes.

Q. How long have you been with InvaTech?

A. Since 2013.

Q. Did you have prior experience in the pharmaceutical industry?

A. Yes. Prior, I was with Sandoz.

Q. Based on your experience, did losing RL Fine as an API supplier delay InvaTech's launch of generic Daraprim?

MS. STEWART: Objection.

THE COURT: Overruled.

THE WITNESS: Yes.

BY MS. HOFFMANN:

Q. When do you think InvaTech would have received FDA approval if RL Fine had continued as InvaTech's supplier?

MS. STEWART: Objection, your Honor; speculation.

THE COURT: Hold on just one second.

Overruled.

BY MS. HOFFMANN:

Q. You may answer the question.

A. Can you repeat it?

Q. Sure.

When do you think InvaTech would have received FDA approval if RL Fine had continued as InvaTech's supplier?

A. Around Q4 of 2018 or 2019.

Q. Was that 2019?

A. Yes.

Q. When do you think InvaTech would have launched generic Daraprim if RL Fine had continued as API supplier?

MS. STEWART: Objection; calls for speculation.

THE COURT: Overruled.

THE WITNESS: Within six months after approval.

BY MS. HOFFMANN:

Q. So approximately when?

A. Q4 2019.

Q. Is that approval or launch?

A. No, launch.

Q. Launch.

Sitting here today, when do you anticipate InvaTech will launch a generic Daraprim product?

A. Q4 2022.

MS. HOFFMANN: Thank you. I have no more questions, Mr. Patel.

THE COURT: Any recross?

MS. STEWART: No, not at this time. Thank you.

THE COURT: Thanks so much.

I just want to make sure I understood correctly your responses to that last chain of questions.

THE WITNESS: Okay.

THE COURT: Do you have your affidavit before you?

THE WITNESS: Yes.

THE COURT: If you could go to page 8, paragraph 43.

THE WITNESS: Yes.

THE COURT: It refers to a trip you made to India?

THE WITNESS: Yes.

THE COURT: And I think that was in 2017; am I right?

THE WITNESS: Yes.

THE COURT: Do you remember when, what month?

THE WITNESS: Around September/October.

THE COURT: I think that's it for my questions.

Counsel, do you have any additional questions based on the questions I put to this witness?

MS. HOFFMANN: No further questions, your Honor.

MS. STEWART: No, your Honor.

THE COURT: Thank you.

You may step down. Thank you.

THE WITNESS: Thank you.

(Witness excused)

THE COURT: Next witness?

MR. MEIER: Your Honor, the government calls, as its next witness, Satya Valiveti. That's S-a-t-y-a V-a-l-i-v-e-t-i. That will be my colleague, Mr. Weingarten, for the government.

THE COURT: Sir, if you could come up here and take the witness stand.

SATYA VALIVETI,

called as a witness by the Plaintiffs,

having been duly sworn, testified as follows:

THE COURT: Now, sir, the ventilation system has been tested here, and, if you wish, you may remove your mask.

THE WITNESS: Sure. Thank you.

THE COURT: Yes.

Please give us your full name.

THE WITNESS: My name is Satya Rayana Valiveti.

THE COURT: Could you spell your first name, please.

THE WITNESS: S-a-t-y-a, Rayana R-a-y-a-n-a.

THE COURT: Now, I have given you poor instructions.

Can you lower that mic even more? Really push it down. Yes, good. Much better.

How do you spell your last name?

THE WITNESS: V-a-l-i-v-e-t-i.

THE COURT: And you're about to be handed a document which is -- no, no, no.

MR. WEINGARTEN: If I may, your Honor, this witness does not have a written direct.

THE COURT: Yes, I have the deposition, not an affidavit. Thank you.

Counsel.

DIRECT EXAMINATION

BY MR. WEINGARTEN:

Q. Good afternoon, Mr. Valiveti.

A. Good afternoon.

Q. My name, again for the record, is James Weingarten, with the Federal Trade Commission, on behalf of the plaintiffs. I'm going to ask you several questions today. Please speak up.

A. Sure.

Q. Please speak slowly. Thank you.

I'd like to start by asking you a little bit about your background.

Very briefly, sir, what do you do for a living?

A. So I'm a CEO at Stira Pharmaceuticals.

THE COURT: Excuse me one second.

We're going to try to adjust the volume issue, so please be patient with us a little bit.

Thank you, Mr. Valiveti. Continue.

MR. WEINGARTEN: Sure.

BY MR. WEINGARTEN:

Q. In addition to being CEO of Stira Pharmaceuticals, do you own any other businesses?

A. Yes. I own Reliant Specialty LLC. I'm a partner in the company.

Q. Who is the other partner?

A. Sandhya, S-a-n-d-h-y-a, last name Kantamaneni, K-a-n-t-a-m-a-n-e-n-i.

Q. Do you have a familial relation with Ms. Kantamaneni?

A. My wife.

Q. Besides Reliant, do you own any other companies?

A. Specialty PharmaSource LLC.

Q. And are there any other co-owners of Specialty PharmaSource?

A. Yes. My wife.

Q. We'll get to those companies in a second.

How long have you worked in pharmaceuticals?

A. Close to 20 years.

Q. Do you have any advanced degrees related to pharmaceuticals?

A. Yes. I have my Ph.D. in pharmaceutical sciences.

Q. Briefly, sir, let's just talk about what each of those companies that you mentioned does.

What does Stira Pharmaceuticals do?

A. Stira is a product development and manufacturing company. So we do injectable products in terms of research and development and also provide analytical services to various pharmaceutical industries.

Q. And what does Reliant Specialty do?

A. So Reliant Specialty is a wholesale distributor for the clinical trial supplies.

Q. What does that mean in layman's terms, if you could, please, sir? Could you please provide more description of what it is that Reliant does?

A. Reference listed drugs, short form RLD, and generic products for the clinical trials of either bioequivalency testing for -- to file FDA for product approvals.

Q. Does Reliant source drugs for commercial sale or resale to patients?

A. No.

Q. And could you please describe what Specialty PharmaSource does?

A. Similar to Reliant Specialty, other than geographical location.

Q. Are you the person at Reliant who is responsible for sourcing RLD?

A. That's right.
Q. Are you also the person at Specialty Pharma --
A. That's right.
Q. -- wait, let me finish the question, please. Sorry.
Are you also the person at Specialty Pharma who is responsible for sourcing RLD?
A. Right. That's right.
Q. Were you the person responsible for sourcing RLD at Reliant between 2017 and 2019?
A. Yes.
Q. And the same for Specialty Pharma?
A. Yes.
Q. Does Reliant have a website?
A. Yes.
Q. When did Reliant first get a website?
A. 2013.
MR. WEINGARTEN: Ms. Guy, could we please put Government Exhibit 4064 on the screen. I'd like to introduce this.
Q. Is Government Exhibit 4064 a printout or copy of Reliant's website?
A. Yes.
MR. WEINGARTEN: Your Honor, at this time, I'd move to admit Government Exhibit 4064.
THE COURT: Received.

(Government's Exhibit 4064 received in evidence)

MR. WEINGARTEN: Thank you.

BY MR. WEINGARTEN:

Q. Let's take a look, sir, at the description of Reliant's business that's on its website.

I'd like you to look at the very top box. There's a picture of a gentleman doing a chemical analysis.

What is the headline, sir, in bright big blue letters at the top of your website?

A. "We Supply Innovator Products/Reference Listed Drugs."

Q. Underneath where it says, "Welcome to Reliant Specialty," it says, in part, "Our experience as pharmaceutical distributors combined with our international network of pharmaceutical drug wholesaler partners makes it possible for Reliant Specialty to procure branded innovator samples/reference listed drugs for bioequivalence and clinical trials from almost anywhere in the world."

Do you see that?

A. Yes.

Q. Is that an accurate description of Reliant's business?

A. Yes.

Q. Was that description part of Reliant's website since its creation in 2013?

A. Yes.

Q. Not to belabor the point, but under the left-hand, there's

a box that says "Our Services."

Do you see that?

A. Yes.

Q. And the first sentence under there, could you please read that first sentence that starts "pharmaceutical innovator"?

A. Yeah. "Pharmaceutical innovators products/reference listed drugs for the development of bio similar and abbreviated new drug applications."

Q. That's sometimes abbreviated ANDA?

A. That's right.

Q. And has that information been on this home page for Reliant since 2013?

A. Yes.

Q. Is that an accurate description of Reliant's business?

A. Yes.

MR. WEINGARTEN: You can take that down, please, Ms. Guy.

Q. Who is Reliant's main client?

A. We have several clients.

THE COURT: What types of companies?

MR. WEINGARTEN: Fair.

BY MR. WEINGARTEN:

Q. What type of companies are your clients, sir?

A. So pharmaceutical companies. Majority of them are generic companies.

Q. Is Dr. Reddy's Laboratories one of Reliant's clients?
A. That's right.
Q. How would you describe Dr. Reddy's in terms of its -- and I don't need an exact number -- but its importance or its share of Reliant's business?
A. Dr. Reddy's is one of the top client for us.
Q. Not just for Dr. Reddy's, but generally, how many products, RLD products, does Reliant source per year?
A. For Dr. Reddy's?
Q. Not just for Dr. Reddy's, sir; as a general matter in a given year.
A. So close to 50, 60 products. Some of them are repeat orders.
Q. Some are what?
A. Recurring orders.
Q. I see.

And how many -- take away the recurring orders. How many different RLD products would you say in a given year Reliant sources?
A. Fifty to sixty products.
Q. How many products, in Reliant's history, has Reliant started the effort to source, but then been unable to source the quantity the client requested?
A. I don't have an exact number on top of my head, but close to 20.

Q. And that's over the lifetime of your experience at Reliant?
A. Every year.
Q. I'd like to talk to you about how Reliant sources its products for its clients.

Now, are you familiar with the term "open distribution" of pharmaceutical products?
A. Yes.
Q. What does "open distribution" mean with respect to pharmaceuticals, as you understand it?
A. So as per my understanding, open distribution means drugs that are available to the pharmacies without any restrictions.
Q. When you say pharmacies without restrictions, are there a kind of pharmacies you're thinking of?
A. Retail pharmacies.
Q. Are you familiar with the term "closed distribution"?
A. Yes.
Q. Now, is there a difference, in your understanding, of the kinds of pharmacies that can receive a drug in closed distribution versus open distribution?
A. Yes.
Q. What kind of drugs, typically, in your experience -- strike that.

What kind of pharmacies, in your experience, distribute drugs that are in a closed distribution system?
A. So even retail pharmacies could get the products that are

in the closed distribution. Also, specialty pharmacies.

Q. Are closed distribution drugs more or less likely to be distributed through retail pharmacies than an open distribution drug?

A. That's right, they're less likely available to retail pharmacies.

Q. Would a drug distributed, in your experience, in closed distribution be more or less likely to be distributed through a specialty pharmacy?

A. That's right.

Q. So more likely or less likely through specialty?

A. More likely through specialty pharmacies.

Q. Okay.

How does a drug being in open or closed distribution impact Reliant's ability to source the reference listed drug?

A. It does a lot because sometimes the manufacturer denies the supply of the products, citing a class of trade.

Q. When you say "class of trade," what do you mean?

A. Class of trade is a retail specialty or wholesale distribution.

Q. Can you elaborate? What do you mean that restrictions on class of trade impact how you source RLD?

A. Some of the products are not available to source for us as Reliant because they only distribute to the doctor offices or specialty pharmacies.

Q. Let's talk a little bit about the exact process that Reliant uses to source RLD.

How, in general, does the process start when Reliant is going to source RLD for a client? How does that get going?

A. First, client bring inquiry to us for the particular drug sourcing. Then --

Q. Let me stop you there.

When they make an inquiry, the client or the potential client, is it for a particular quantity of drug?

A. Sometimes.

Q. What do you do next after the client approaches and makes an inquiry about a particular RLD?

A. Then we approach manufacturer, the wholesale distributor, which we have an account with, AmerisourceBergen, then we will ask them whether this drug is available for us to source.

Q. Sorry, go ahead.

A. Then, you know, sometimes they'll send us some documents to fill it, then they'll share with the manufacturer for approvals.

Q. Let me stop you and back up a second.

When Reliant contacts the wholesaler to inquire, what information are you specifically inquiring about with the wholesaler?

A. So drug product name and NDC code. It's a product code.

Q. What information are you looking for from the wholesaler

when you give them the name and the NDC code?
A. Whether that product is available for Reliant to source.
Q. And do you ask for a price quote?
A. Yes, price quote and availability.
Q. Do you ask for lead time?
A. Yes.
Q. What does lead --
A. That's availability.
Q. After you receive -- let's assume for a second that the wholesaler responds with price and availability and lead time.

What do you do next?

A. So if the wholesaler comes back to us, okay, this product is approved for Reliant to source, then we will send a quotation to customer.
Q. When you send the quotation to a customer, do you send them a pro forma invoice?
A. No. We send an estimate.
Q. I see.

What happens next, after the estimate, if the customer wants to proceed, typically?

A. They will issue a purchase order.
Q. And what is a purchase order in this context? Can you describe one, please?
A. So, basically, the customer would issue so-and-so product and the quantity and the price.

Q. And is purchase order sometimes abbreviated PO?
A. Yes.
Q. Now, when Reliant sends to a client an estimate based on the information Reliant got from the wholesaler, is Reliant sending a guarantee of delivery of that RLD?
A. No.
Q. And when Reliant sends an estimate to the client of lead times or availabilities, is that a guarantee Reliant can meet those times?
A. Those are tentative timelines. Those are like approximate timelines.
Q. When Reliant sends an estimate to a client, is that a guarantee that Reliant has the RLD in its possession?
A. No.
Q. Now, if the customer decides to move ahead and issues the purchase order, what happens next?
A. Then we are going to send them a pro forma invoice for the payment.
Q. And you say "for the payment." Is that a payment on delivery or a prepayment?
A. Prepayment.
Q. What is the typical amount of prepayment that you ask from a client?
A. Majority of time, hundred percent.
Q. I'm sorry, I can't hear you.

A. Hundred percent prepayment.
Q. Is prepayment a condition of Reliant beginning the work of sourcing?
A. Yes.
Q. And when is the rest of the payment due?
A. Prepayment is they are going to pay entire payment in advance.
Q. If there was a 50 percent prepayment, for example, when would the payment balance be due?
A. There wasn't a certain procedure. It's depending on the client to client.
Q. Okay.
A. Sometimes paid upon sourcing, sometimes paid upon shipping, yeah.
Q. Why do you require prepayment?
A. Because these are specialty products, and sometimes when we source the products from a wholesale distributor, those are nonreturnable.
Q. Now, let's assume that the client has made the prepayment and asked Reliant, okay, please go ahead and source the RLD for us. What do you do first to try to source the RLD, typically?
A. We approach wholesale distributor.
Q. And you gave one example before of -- let me strike that.
Is AmerisourceBergen an example of a wholesale distributor you might approach?

A. Yes.
Q. And what happens if the drug is available to Reliant from the wholesale distributor, what do you do next?
A. We'll issue a purchase order. Then it takes a week to get the product from them if it is approved.
Q. So Reliant issues the purchase order to the wholesaler?
A. Wholesaler, yes.
Q. In your experience, did you say it typically takes a week to get it back from the wholesaler?
A. That's correct.
Q. And what do you do with the drug once you get it back from the wholesaler?
A. So we'll share the lot and expiration to the customer, then they'll arrange pickup.
Q. That was the example of if the wholesaler agrees to supply Reliant.

What would you try if you contact a wholesaler, and the wholesaler says, no, we cannot supply Reliant with the RLD?
A. Yes, often happens we do not have -- we may not have access to certain products, then we approach other distributors.
Q. Have you ever tried to talk to the manufacturer directly to purchase RLD?
A. Sometimes wholesale distributor will send us a note saying that we need to contact the manufacturer.
Q. And then I think before, we talked about manufacturer, you

said you will try to source it from another third party; is that right?

A. That's right.

Q. So what is an example of another kind of company from whom you would source? What do you mean by that?

A. So we source products from other similar distributors, like Reliant, where they have access.

Q. So if the wholesaler says it will not supply, one option is to try to seek source from other companies like Reliant?

A. Like Reliant.

Q. Is that common, that RLD sourcing firms will contact each other to try and source RLD?

A. That's right.

Q. Has a company called ProSupplier ever asked for Reliant's help sourcing RLD?

A. Yes.

Q. Going back how long -- strike that.

When was the first time Reliant asked -- strike that.

When was the first time ProSupplier asked Reliant for help sourcing RLD?

A. I don't remember exact year, but I know them a long time.

Q. Is it more than five years ago that ProSupplier may have first contacted Reliant for help?

A. Yes, yes.

Q. Over the years, have they asked for help about various

products, one product?
A. Lately, no inquiries; in the past, yes, they asked for several products.
Q. Has ProSupplier ever asked Reliant for help sourcing Daraprim?
A. Yes.
Q. Did you agree to help ProSupplier source Daraprim?
A. No. The pricing did not work.
Q. Can you elaborate more? Why did Reliant not agree to help provide or source Daraprim to ProSupplier?
A. Because they're also suppliers like Reliant. The pricing which I quote, then they're going to add on some margin to the customer, so they felt pricing is high.
Q. So if -- when ProSupplier approached Reliant for help with Daraprim, was it your understanding -- what was your understanding that ProSupplier would then do with the price if you had supplied it to ProSupplier?
A. They go silent. They don't really response.
Q. I'm sorry, I didn't hear you.
A. When they give a quotation, if they like you, they're going to come back to us; if they don't, they went silent.
Q. Would you expect ProSupplier to add its own markup on top of what you would charge?
A. Yes.
MS. STEWART: Objection; foundation.

THE COURT: Overruled.

Q. When was the last time that ProSupplier -- strike that.

How often was ProSupplier asked for Reliant's help to source Daraprim?

A. I think one or two times.

Q. Do you remember approximately when that was?

A. I think sometime '17.

Q. Now, in open distribution, how long does it typically take Reliant to source RLD going through those steps, from the moment the client says we're interested to delivery to client? What's the typical time in open distribution?

A. Less than a week.

Q. Less than a week? Okay.

I want to ask you a little bit, continuing on discussion about how Reliant sources, I want to talk to you a little bit about CentraState.

Now, we talked about companies that you own. Does your wife own a pharmacy?

A. Yes.

Q. And what is the name of that pharmacy?

A. CentraState Specialty.

Q. What kind of pharmacy is CentraState?

A. It's a retail pharmacy.

Q. Is it affiliated with a hospital, a CVS, a standalone?

A. It's an outpatient pharmacy.

Q. Is it located in a strip mall or a hospital or a medical center?
A. In the medical center.
Q. What state, please?
A. New Jersey.
Q. How long has your wife owned CentraState?
A. Since 2016, December.
Q. If you cannot source a product from the wholesaler or the manufacturer or other RLD sourcing firms, would you use CentraState to help source?
A. If the product is available, then only we can -- I can try.
Q. Is it your understanding -- strike that.

Is CentraState allowed to buy pharmaceutical products and resell them for nonretail use?
A. Yes.
Q. Does CentraState work with a distributor who supplies specialty pharmacy products to CentraState?
A. Yes.
Q. What is the name of that distributor?
A. ASD Healthcare.
Q. Could you please walk us through the steps of how Reliant might use CentraState to help source an otherwise unavailable RLD?
A. So we use very --
Q. Just speak up and slowly, please, sir.

A. We source products from CentraState very rarely.
Q. What's the first step, sir? Does Reliant make a request to CentraState?
A. Yes.
Q. What happens then?
A. So we'll ask them whether the particular product is available. Then, if it's available, then we'll procure the product.
Q. When you say if the product is available, do you mean available from ASD?
A. Yes.
Q. And so you'll ask if it's available, CentraState will then purchase the product from ASD?
A. No. We have to -- if it's available, then we'll ask them to purchase, yes.
Q. And after CentraState purchases the product, is it CentraState that pays ASD?
A. Yes.
Q. And then does Reliant purchase the product, then, from CentraState?
A. Reliant will pay for CentraState.
Q. And then Reliant gets delivery from CentraState, correct?
A. Right.
Q. And then does Reliant deliver the product to its client?
A. That's correct.

Q. And I know you said "rarely." How often has Reliant used CentraState to acquire RLD?

A. The time period?

Q. Oh, over the lifetime, let's say, of your relationship between Reliant and CentraState.

A. Yearly, I think around three, four times, we source.

Q. I'm sorry, I didn't hear the first time.

A. Three to four times.

Q. Per year?

A. Per year.

Q. We'll get to more on this in a second, but did Reliant use CentraState to help acquire some Daraprim in 2018?

A. Yes.

Q. Was that example, Daraprim, of Reliant using CentraState the only time Reliant used CentraState in 2018, or were there other times?

A. For Daraprim?

Q. No, I'm sorry, for any drug in 2018.

A. I don't have -- I don't remember, but there were times.

Q. Let's turn, then, specifically to Reliant's efforts to source Daraprim.

Now, we talked about Dr. Reddy's, and Dr. Reddy's is one of Reliant's main clients, right?

A. Right.

Q. Is Dr. Reddy's Laboratories also abbreviated DRL?

A. Yes.
Q. How long has Reliant been working with Dr. Reddy's?
A. Since 2013.
Q. In late 2017, did Dr. Reddy's ask Reliant to estimate a cost to source Daraprim RLD?
A. Yes.
MS. STEWART: Objection; leading.
THE COURT: I assume this is an introductory question for a line. Am I right?
MR. WEINGARTEN: It is.
THE COURT: Okay.
MR. WEINGARTEN: Thank you, your Honor.
BY MR. WEINGARTEN:
Q. How much Daraprim did DRL ask you to source?
A. Five bottles.
Q. Did you have any understanding why DRL wanted you to source Daraprim RLD?
A. Yes.
Q. What did you think DRL needed it for?
A. For the product development purpose.
Q. Do you have any more specific understanding of product development purpose there?
A. I don't know. I can say it's a generic product company. They might be using for product development, and it would ultimately be used for filing with the FDA.

Q. After DRL asked you to look into sourcing Daraprim in late 2017, what did you do first?

A. So I contacted AmerisourceBergen, ASD, to source this product. I sent an email stating that I need five bottles of Daraprim, then asked them the pricing and lead time.

MR. WEINGARTEN: Ms. Guy, could you please put GX 3126 on the screen. And I'd like you to highlight the email contents. Both emails is fine. Thank you.

BY MR. WEINGARTEN:

Q. Now, is GX 3126 an email chain between Reliant and a company called ICS-Connect?

A. Yes.

Q. What is ICS-Connect?

A. So they have a -- ASD and AmerisourceBergen, they support RLD sourcing through ICS-Connect.

Q. So is ICS-Connect an affiliate of ASD?

A. That's right.

Q. Strike that -- yes, okay. Thank you.

The email address at the bottom, the bottom email, it says from Sandhya. That's sandhya@reliantspecialtyrx.com.

Do you see that?

A. Yes.

Q. It's dated December 20, 2017.

Do you see that?

A. Yes.

Q. And Sandhya is your wife's name, right?
A. That's right.
Q. Is that your name at the bottom, Satya Valiveti?
A. Yes.
Q. So even those these emails are to and from Sandhya, did you author and read these emails?
A. Yes.
Q. Do you sometimes use your wife's email address?
A. Yes.

MR. WEINGARTEN: Your Honor, I'd move to admit GX 3126.

THE COURT: Received.

(Government's Exhibit 3126 received in evidence)

MR. WEINGARTEN: Thank you.

BY MR. WEINGARTEN:

Q. So let's focus on the bottom email, please. The message is from sandhya@reliantspecialtyrx, and it's dated December 20, 2017.

Do you see that, sir?

A. Yes.
Q. And the message asks, "Please let me know the availability and pricing on the following product."

What product are you asking about there, sir?

A. Daraprim.
Q. And what quantity of Daraprim?

A. Five bottles.
Q. Did you send this message as part of getting an estimate for sourcing Daraprim for DRL?
MS. STEWART: Objection; leading.
THE WITNESS: Yes.
THE COURT: I think that's just a summary, and I will let both counsel do it, to just make sure the record is clear, given communication issues.
MR. WEINGARTEN: You can take down that one, Ms. Guy, and we'll talk about the top email on the same document, please.
BY MR. WEINGARTEN:
Q. Did Mr. Benji Belleli, B-e-l-l-e-l-i, write you back?
A. Yes.
Q. And looking at GX 3126, what did he tell you?
A. So they asked me to contact the manufacturer directly.
Q. Did Mr. Belleli give you some contact info?
A. Yes.
Q. Whose contact information did he provide?
A. Anne Kirby.
Q. Had you ever talked to Anne Kirby before?
A. No.
Q. How often, in your experience, does a wholesaler tell you to contact a manufacturer directly?
A. I can remember a couple of times.

Q. And that's a couple of times over your career?
A. Yes.
Q. Did you email --
MR. WEINGARTEN: You can put that down, Ms. Guy. Thank you very much.
Q. Did you email Ms. Kirby at that email address about Daraprim?
A. Yes.
MR. WEINGARTEN: Ms. Guy, could you please put GX 3127 on the screen. If you can please zoom in, so we can see more. Thank you.
Q. Is GX 3127 an email you sent to Ms. Kirby?
A. Yes.
MR. WEINGARTEN: I'd like to move to admit GX 3127 into evidence, please, your Honor.
THE COURT: Received.
(Government's Exhibit 3127 received in evidence)
BY MR. WEINGARTEN:
Q. Let's take a look at the document, please, sir. The address is to akirby@vyera.com.
How did you get her email address?
A. The AmerisourceBergen gave me the email.
Q. That's the email we just looked at from ICS?
A. Yes.
Q. It says, "cc: Sandhya" and "From: Sandhya," and that's

your wife's email address, right?
A. Yes.
Q. Did you write this email?
A. Yes.
Q. The date of the email is January 3rd, 2018, correct?
A. Yes.
Q. What are you asking Ms. Kirby in this email?
A. So I'm requesting for approval for five bottles of Daraprim.
Q. Was this also part of your work on behalf of Dr. Reddy's?
A. Yes.
Q. Did you specify the NDC code for Daraprim?
A. Yes.
Q. And you specified the kind of bottle that you needed, right?
A. Yes.
Q. And what quantity, again, sir? I'm not sure.
A. Five bottles.
Q. Did you offer to supply any additional information she needed?
A. No, I never heard from her.
Q. Okay. The question was, sir: Did you ask at the bottom, "Please let me know if you need additional information"?
A. Yes.
Q. And did she ever reach out to you?

A. No.
Q. Did you ever hear from Ms. Kirby?
A. No.
Q. I want to just focus on the top sentence there. You said, "This is Satya Valiveti from Reliant Specialty LLC. Would like to purchase the following product for chemical analysis for research and development."
Do you see that, sir?
A. Yes.
Q. What did you mean when you wrote "chemical analysis for research and development"?
A. So for the product development.
Q. Can you be more specific, sir?
A. So it's basically used for the chemical analysis for the generic product development. So we call it research and development.
Q. I think we established, Ms. Kirby, did she ever respond to your email?
A. No.
Q. Did anyone from Vyera respond to your email?
A. No.
Q. Did you also try calling Ms. Kirby?
A. Yes, I did.
Q. Did you leave voicemails for Ms. Kirby?
A. Yes.

Q. How many?
A. One time.
Q. Did Ms. Kirby respond to your voicemails?
A. No.
Q. In the voicemails, did you repeat the information that you had put in this email --
A. Yes.
Q. -- that we're looking at, GX 3127?
A. That's right.
Q. Did anyone from Vyera call you back in response to your voicemails?
A. No.
Q. And when, approximately, do you think you left those voicemails for Ms. Kirby?
A. I don't remember exact timelines. It would be right after a week I sent her this email.
Q. So within a week of this email, you believe?
A. Yes.
Q. Okay.

MR. WEINGARTEN: Ms. Guy, you can take that document down. Thank you very much.

Q. So let's talk about what happens after the email and the voicemails a little bit.

Strike that. Let's talk about a company called Fera.

Now, we've been talking about DRL. In January 2018,

right around the same time of the email we were just looking at, while you were working on getting Daraprim for DRL, did a company called Fera also ask Reliant to procure some Daraprim?
A. Yes.
Q. How much Daraprim did Fera ask you for?
A. I don't remember exact quantity. I think it's two bottles.
Q. Would it help, sir, refresh your recollection if we looked at some deposition testimony you gave on that topic?
A. Sure.
MR. WEINGARTEN: Ms. Guy, could we please look at the deposition of Mr. Valiveti, page 93 of the deposition, and it's lines 11 to 15.
Q. Don't read it out loud, sir, just read that to yourself, and let me know when you've had a chance to read it.
Does that refresh your recollection as to how many bottles of Daraprim Reliant asked you to acquire?
A. Yes. Two bottles.
Q. So did Reliant -- did Fera ask you to procure two bottles?
A. Yes.
MR. WEINGARTEN: Okay. You can take that down. Thank you, Ms. Guy.
Q. Did you have an understanding of why Fera wanted to source Daraprim RLD?
A. Product development.
Q. And what product were they developing, in your

understanding?
A. The generic product.
Q. A generic of what, sir?
A. Daraprim.
Q. Did you contact ICS, the AmerisourceBergen division, again in response to Fera's inquiry?
A. I don't remember contacting them.
Q. Why not?
A. Since they already mentioned that I need to contact manufacturer.
Q. Did you contact Vyera again in response to Fera's request for RLD?
A. No.
Q. And why not?
A. Because I did not get a response from them.
Q. Did you try to source the Daraprim for Fera from any other RLD sourcing firms?
A. Yes.
Q. Were they able to supply you two bottles of Daraprim for Fera?
A. No.
Q. Were you eventually able to acquire two bottles of Daraprim for Fera?
A. Yes.
MS. STEWART: Objection; leading. This whole line of

questioning is leading.

THE COURT: Overruled.

BY MR. WEINGARTEN:

Q. How did you acquire two bottles of Daraprim for Fera?

A. From CentraState.

Q. Can you walk us through from whom did CentraState acquire the Daraprim?

A. ASD Healthcare.

Q. Why was CentraState able to buy it from ASD?

A. Because they have access.

Q. Why do they have access?

A. I don't know.

Q. Is CentraState a client of ASD?

A. Yes.

Q. Did you deliver the two bottles to Fera that CentraState had acquired?

A. Yes.

Q. Do you recall when you delivered those two bottles?

A. No, I don't remember the timelines.

MR. WEINGARTEN: Ms. Guy, could you please put Government Exhibit 3145 on the screen.

I believe, your Honor, this is already in evidence as part of Government Exhibit 9002.

I don't know if it's possible, Ms. Guy, to rotate it?

MS. GUY: I'm not sure.

MR. WEINGARTEN: That's okay. We can work with it. Actually, instead of the barcode, Ms. Guy, can you please do the shipping, the to and the from, on the upper part there. Yes, and then above that. Keep going up. Thank you.

BY MR. WEINGARTEN:

Q. Okay, sir, I want to show you this.

Do you recognize this document?

A. Yes.

Q. What is it?

A. It's a shipping label.

Q. From whom?

A. From Reliant.

Q. To whom?

A. To Fera Pharma.

Q. If you look in the upper right-hand corner, what's the ship date, sir?

A. January 30th.

Q. I see January 29.

A. January 29th, yes. Sorry.

Q. That's okay.

So does that help refresh your recollection, sir, as to when you shipped Daraprim to Fera?

A. Yes.

Q. What was the date?

A. January 29th.

MR. WEINGARTEN: And just to make sure this is, in fact, the Daraprim, can we turn to the next page of the document, please, Ms. Guy, Government Exhibit 3145-002.

Q. What is this, sir?

A. Daraprim. It's a packing slip.

Q. Is this a Reliant packing slip?

A. Yes.

Q. What product does it say was packed?

A. Two bottles of Daraprim.

Q. And how much did Reliant charge Fera for those two bottles of Daraprim? Strike that.

MR. WEINGARTEN: Let's move to the next page, please, Ms. Guy, 3145-003.

Q. What is this document, sir?

A. This is an invoice.

Q. It's from whom?

A. From Reliant to Fera Pharma.

Q. And what product is this for?

A. Daraprim.

Q. Was this included in your package mailing the Daraprim to Fera?

A. I believe so.

Q. How much did Reliant charge Fera for two bottles of Daraprim?

A. $230,500.

Q. 230,500, correct?
A. Yes.
Q. That's 115,250 per bottle?
A. That's right.
MR. WEINGARTEN: You can take that down, please, Ms. Guy.
Q. So we talked a little bit about Fera there.
So Fera requested, and you were able to supply, two bottles; is that right, sir?
A. That's right.
Q. Using CentraState?
A. That's right.
Q. Let's turn back to DRL now. That was January of 2018. Let's turn back to DRL.
MR. WEINGARTEN: Ms. Guy, could you please -- strike that.
Q. Did there come a time, sir, when DRL agreed to move forward with your sourcing of Daraprim?
A. Yes.
MR. WEINGARTEN: Let's look at Government Exhibit 3562, please.
This document, your Honor, is already in evidence. I believe it was admitted with Government Exhibit 9010.
Let's take a look -- Ms. Guy, sorry, can you zoom in on the bottom email, please? It's the one from Ramesh

Rachapudi. Thank you.

Q. The bottom email is from Mr. Rachapudi.

Where does he work?

A. Dr. Reddy's.

Q. What is date of the email, please?

A. March 6, 2018.

Q. Who is it to?

A. To sandhya@reliant.

Q. Even though it's to your wife's email, did you receive this email?

A. Yes.

Q. Did you read it at the time?

A. Yes.

Q. What do you understand Mr. Ramesh to be communicating here?

A. So they issued a purchase order for RLD samples of Daraprim.

(Continued on next page)

Q. That's on March 6, 2018?
A. Yes, sir.
MR. WEINGARTEN: Ms. Guy, let's look at the e-mail above it, the top e-mail in the chain.
Q. Is this your response, sir?
A. Yes.
Q. Even though it's from Sandhya's e-mail that's your name at the bottom, right?
A. Yes.
Q. Did you write this response?
A. Yes.
Q. What's the date?
A. March 6.
Q. 2018?
A. 2018.
Q. What you explaining to Mr. Rachapudi of Dr. Reddy's?
A. They sent pro forma invoice for advanced payment.
Q. You wrote to Mr. Rachapudi, we will deliver the product within a week from the payment receipt. Do you see that?
A. Yes.
Q. Was to your intention at the time, to deliver the product within a week?
A. That's right.
Q. What was the basis for your estimate that it might just take a week to receive the product and deliver it to DRL?

A. Based on the source, we thought we -- we thought we were going to supply within a week.

MR. WEINGARTEN: Ms. Guy, could you please turn to the next page of this document, 3562-02.

Q. What is this document, sir?

A. A pro forma invoices.

Q. Is this the attachment to that e-mail we were just looking at?

A. Yes.

Q. It's from Reliant, right?

A. Yes.

Q. Who are you billing on this invoices?

A. Dr. Reddy's.

Q. To whom are you shipping the product, if you get it?

A. Cerovene.

Q. Under the word terms it says 100 percent advance. Do you see that?

A. Yes.

Q. What does that indicate?

A. It's a prepayment.

Q. Does it mean you're asking for full prepayment of the entire cost of the drug?

A. That's right.

Q. In this case, sir, what is the drug that's being described on this invoices?

A. Daraprim.
Q. How many bottles of Daraprim?
A. Five bottles.
Q. How much per bottle?
A. $110,000.
Q. How much would Dr. Reddy's have to prepay Reliant to begin the process of sourcing Daraprim five bottles?
A. $550,000.
MR. WEINGARTEN: You can take that down, Ms. Guy. Thank you.
Q. Did DRL actually make that prepayment?
A. Yes.
Q. How did they make the payment, by what mechanism?
A. Wire transfer.
Q. For the full amount of $550,000?
A. Yes.
Q. How soon after the pro forma invoice did you receive that prepayment?
A. I don't remember.
Q. Was it a long time coming or do you remember anything, approximately?
A. I believe it may have taken like three weeks.
Q. Was Reliant able to acquire five bottles of Daraprim RLD after this discussion with Dr. Reddy's?
A. Yes.

Q. How?
A. Reliant procured from CentraState.
Q. Let me stop you right there. How did CentraState acquire the bottles?
A. They purchased it from ASD.
Q. Did they place an order for all five bottles with ASD?
A. Yes.
MR. WEINGARTEN: I'd like to introduce Government Exhibit 3130, please, Ms. Guy. Thank you.
Q. Actually, what is this document, sir?
A. It's an order confirmation.
MR. WEINGARTEN: Ms. Guy, can you do the header of the e-mail. Thank you so much.
Q. Who is this order confirmation from?
A. ASD Health Care.
Q. Who is it to?
A. Sandhya Kantamaneni.
Q. Is that your wife?
A. Yes.
Q. What's the date?
A. March 4.
Q. I'm sorry, sir. Is it March 4 or April?
A. April 4.
Q. 2018?
A. That's correct.

MR. WEINGARTEN: Ms. Guy, can you now go to the body of the ASD confirmation.

Q. It says there is an order date. Do you see that, sir?

A. Yes.

Q. Strike that. Let me do that first, actually.

MR. WEINGARTEN: Your Honor, I'd like to admit into evidence GX-3130, please.

THE COURT: Received.

(Government Exhibit 3130 received in evidence)

Q. Do you see the order date, sir?

A. Yes.

Q. Does that reference the date on which CentraState placed an order with ASD?

A. Yes.

Q. What date is that?

A. April 4.

Q. Of 2018?

A. 2018.

Q. 2018?

A. Yes.

Q. What time?

A. 9:33 a.m.

Q. What product was CentraState ordering, according to this web order confirmation?

A. Daraprim.

Q. How much Daraprim?
A. Five bottles.
Q. How much per bottle?
A. $75,000.
Q. What's the total cost then that CentraState paid to ASD for this five bottles of Daraprim?
A. $375,000.
MR. WEINGARTEN: Ms. Guy, you can take that one down.
THE COURT: Sir, we are still getting a little feedback. I am going to ask you to just move the mic one way or another, sort of a little away from you. I don't want you to move too far back. If you could just move it down or move it to the side. It moves. Let's see if that works. Thank you.
Q. Did CentraState receive the five bottles of Daraprim that it ordered from ASD?
A. Yes.
Q. When? I'll ask you this. How soon, sir, after the order do you believe you received them?
A. Usually, the next day.
MR. WEINGARTEN: Ms. Guy, could we please look at GX-3131. Can you do the e-mail header and the title, please of the document.
Q. What is this document, sir?
A. It's a shipment confirmation.

Q. Is it from ASD?
A. Yes.
Q. Who is the shipment confirmation to?
A. Sandhya Kantamaneni.
Q. Did you receive the shipment confirmation?
A. Yes.
Q. What's the date of the shipment confirmation?
A. April 4, 2018.
Q. Is the order date, again, April 4, 2018? Do you see that it says order date?
A. Order date, yes.
Q. What's the date the e-mail was sent with the shipment confirmation to Sandhya Kantamaneni?
A. April 5, 2018.

MR. WEINGARTEN: Ms. Guy, can you go to the contents of the document, please.

Your Honor, I would move to admit GX-3131, please.

MS. STEWART: Your Honor, objection. It's not clear to me from the record that the witness has seen this document.

THE COURT: The objection is that counsel does not know if the witness saw this document contemporaneously.

Counsel, may you inquire.

MR. WEINGARTEN: Sure.

Q. On or about the time that this e-mail is dated, did you see it?

A. Yes.
Q. Is that a yes?
A. Yes.
Q. And, again, what is the product that ASD is confirming that it shipped?
A. Daraprim.
Q. How much Daraprim?
A. Five bottles.
Q. To whom did ASD ship five bottles of Daraprim?
A. CentraState.
Q. Is that the same CentraState pharmacy that your wife owns?
A. That's right.
MR. WEINGARTEN: I am not sure if I got the admission. I move to admit GX-3131, please.
THE COURT: Received.
(Government Exhibit 3131 received in evidence)
MR. WEINGARTEN: You can take that down, please, Ms. Guy.
Q. At the time, on April 5, when the bottles shipped, was it your intention to deliver those five bottles to DRL?
A. Yes.
Q. Did CentraState actually receive the five bottles of Daraprim from ASD?
A. Yes.
Q. Was it your intention to transfer the bottles from

CentraState to Reliant?
A. Yes.
Q. Did Reliant ultimately supply any of those five bottles of Daraprim RLD to Dr. Reddy's?
A. No.
Q. Did Reliant ultimately supply any of those five bottles of Daraprim RLD to any of its clients?
A. No.
Q. Let's talk about why not.

Now, after CentraState purchased five bottles of Daraprim RLD from its wholesaler, ASD, did someone from Vyera call CentraState?
A. Yes.
Q. Do you know who?
A. I don't remember.
Q. Do you know what the person wanted?
A. I think it was a sales rep.
Q. I'm sorry?
A. It's a sales local rep.
Q. What did this local sales rep for Vyera want?
A. So what I heard from my wife is they inquiring about the product -- why did CentraState purchase and the doctor name.
Q. Let's break that down a little bit. Is it your understanding that a person from Vyera called asking about the Daraprim that CentraState had purchased?

A. That's right.
Q. What questions did the person from Vyera ask?
THE COURT: With whom did that person speak?
THE WITNESS: The pharmacist at pharmacy.
THE COURT: So they didn't speak to you?
THE WITNESS: No, they didn't.
MR. WEINGARTEN: I would like to introduce it, your Honor, for the effect on the listener.
THE COURT: How did you learn about that conversation? Who told you about the conversation?
THE WITNESS: My wife.
MR. WEINGARTEN: Thank you, your Honor.
Q. What did your wife tell you about the conversation?
A. That the company rep called her inquiring about the product, why the purchase happened, what was the purpose.
Q. The person inquired about what the purpose of the purchase of the Daraprim was?
A. Yes.
Q. What was your wife's reaction to this inquiry from Vyera?
A. She felt nervous.
Q. Why was she nervous?
A. Because they are inquiring about the doctor name and everything.
Q. Why would inquiries about the doctor name, whether there was a doctor who had ordered this Daraprim, why was that cause

for being nervous, in your mind?
A. Once you read about the relationship between the supplier of ASD and the pharmacy is going to be in trouble.
Q. What did you think might happen that would cause CentraState to get in trouble with ASD?
A. I think she assumed that they were going to cancel the account.
Q. By they canceling the account, you mean ASD canceling its account?
A. Yes.
Q. With CentraState?
A. Yes.
Q. Were you also nervous about this?
A. Yes.
Q. I don't want to put too fine a point on it, but I want to get your personal knowledge. Why was Vyera's inquiries making you nervous about the relationship between ASD and CentraState? What did you fear would happen?
A. For me there was no reason, but my wife was nervous. That makes me worried.
Q. I understand. Your wife was nervous because there was a concern about interference -- concern that ASD would be upset with CentraState?
A. Right.
Q. Is that correct?

A. That's right.
Q. Why would that be a problem for CentraState if ASD ended its contract with CentraState?
A. She thought a rep was going to complain to ASD.
Q. The rep being the Vyera rep?
A. Yes.
Q. If the Vyera rep complained and ASD stopped being CentraState's supplier, why is that a problem for CentraState?
A. Because that's the only specialty distributor that CentraState purchased.
Q. Could CentraState continue to do its business without ASD as a supplier?
MS. STEWART: Objection. Calls for speculation.
THE COURT: Overruled.
A. There are other specialty distributors.
Q. Would it be a disruption if ASD dropped CentraState?
A. That I don't know.
Q. Are there patients at CentraState who are on products that ASD supplies?
THE COURT: Counsel, I am going to sustain the objection to leading. I will let you inquire as to why it would be a problem or why someone was worried, but it should come from the witness.
MR. WEINGARTEN: OK.
Q. Was there anything specific, sir, about why it would be a

problem for CentraState if ASD terminated CentraState's relationship?

A. She thought she was going to lose access to particular products.

Q. Did you and your wife think about returning the bottles of Daraprim to ASD?

MS. STEWART: Objection. Leading.

THE COURT: Sustained.

Q. What did you do next, sir, after you talked to your wife about the Vyera sales rep's call?

A. So we wanted to return the product to ASD.

Q. Did you return the bottles to ASD?

A. No. We created a written authorization to return the product to ASD.

Q. And what happened at that point in time? What happened next with respect to the Daraprim bottles?

A. I think after a couple of days we got a call from a person I know that -- he was inquiring of me whether we bought Daraprim and the quantity.

Q. What is the name of the person who called?

A. Peter.

Q. Do you know Peter's last name?

A. It's complicated.

Q. Do you think it would refresh your recollection if we looked at some testimony you gave about Peter?

A. Yes.

MR. WEINGARTEN: Ms. Guy, could we please look at the deposition of Mr. Valiveti, page 117 of the deposition, line 22, to page 118, line 2:

Q. Read to that to yourself, sir.

A. Yes.

Q. Does that refresh your recollection about the last name of Peter?

A. Yes.

Q. What is Peter's last name?

A. Skoutelas.

Q. When Mr. Skoutelas called you, what happened? What did he say?

A. So he was inquiring about the product we purchased.

MS. STEWART: Objection. Hearsay as to what --

THE COURT: Overruled.

A. Then he said an office friend at Vyera wanted to talk to me.

Q. Did you subsequently get on a conference call with a person from Vyera and Mr. Skoutelas?

A. Yes.

Q. When?

A. Around the same day.

Q. Do you remember approximately when that day was or how long after it was that you had received the Daraprim that you had

this call with Mr. Skoutelas and someone from Vyera?
A. I think two or three days after.
Q. Who were the participants on this conference call?
A. Myself and Peter Skoutelas and Kevin Mulleady.
Q. A gentleman named Kevin Mulleady?
A. Yes.
Q. Had you ever known Mr. Mulleady before this call?
A. No.
Q. Had you ever talked to Mr. Mulleady before that call?
A. No.
Q. What did Mr. Mulleady -- how did the call start?
A. I don't remember the exact conversation.
Q. What did Mr. Mulleady say on the call?
A. So he was inquiring about the intent of the purchase.
Q. Can you be more specific.
A. He asked -- I don't remember the exact words. He is trying to get information on why we purchased the product.
Q. Did you answer his questions about why you purchased five bottles of Daraprim?
A. I am -- I did not reveal my client.
Q. Why not?
A. Keep the confidentiality of the client.
Q. Is it your understanding your clients request confidentiality when you are doing purchases of RLD?
A. In this case, no. But the -- but Reliant wanted to keep

confidentiality.

Q. Why did Reliant want to keep the confidentiality of its client in this case?

A. That's the nature of the business, because it's client protection.

Q. Did you tell Mr. Mulleady that you were thinking about returning the bottles to ASD?

A. Yes.

MS. STEWART: Objection. Leading.

THE COURT: Sustained. Stricken.

Q. What did you tell Mr. Mulleady after he inquired about what you were doing with the bottles?

A. He offered me to -- Kevin wanted to take back the bottles.

Q. Let's stop there for a second. What specifically did Mr. Mulleady offer?

A. The price.

Q. When Mr. Mulleady said he could take the bottles, what did you say?

A. We didn't -- we wanted to return to ASD.

Q. What did Mr. Mulleady say after that?

A. He said he wanted to get the bottles.

Q. Get the bottles to whom?

A. For himself.

Q. Did you quote a price to Mr. Mulleady at which you would sell the bottles back to Vyera?

MS. STEWART: Objection. Leading.

THE COURT: Sustained.

Was there any discussion about price?

THE WITNESS: Yes.

THE COURT: Who said what with respect to price?

THE WITNESS: Kevin offered me one price at the purchase price, which was $75,000 per bottle.

Q. What did you say?

A. We said like we can give it to him at higher price.

Q. What price did you say?

A. I don't remember exact price. It's 130,000 per bottle.

Q. Did you and Mr. Mulleady -- what happened next after you said 130,000 per bottle?

A. I didn't say anything, and he agreed to pay.

Q. Did Mr. Mulleady agreed to pay the price you quoted?

A. Yes.

Q. Did Reliant eventually receive the money, the price that you were quoted on that call?

A. Yes.

Q. How much money did Reliant receive?

A. I don't remember the exact number.

Q. Was it in accord with what you had talked to with Mr. Mulleady on the call?

A. Can you repeat, please.

Q. Sure. Was it in accord with what you had discussed with

Mr. Mulleady on the call?

A. I didn't get it.

THE COURT: Did you receive the money?

THE WITNESS: Yes, we received the money.

THE COURT: Was it the full amount that you had agreed upon with Mr. Mulleady?

THE WITNESS: Not the full amount. Some money taken by the Peter.

Q. What do you mean, some money was taken by Peter?

A. Peter gets a commission.

Q. Mr. Skoutelas got a commission?

A. Yes.

Q. And the rest went to Reliant?

A. Reliant.

Q. Did you return the five bottles of Daraprim to Vyera?

A. Yes.

Q. When did you do that?

A. After getting paid.

Q. Where did you return the five bottles of Daraprim that Reliant had purchased for DRL?

A. I met him at the parking lot of Starbucks in Parsippany.

Q. When you say him, who did you mean, sir?

A. Kevin Mulleady.

Q. What happened at your meeting at the Starbucks parking lot in New Jersey?

A. Nothing. It was a very short meeting. I just gave him the bottles.

Q. Where were the bottles when you gave them to Mr. Mulleady?

A. In an envelope.

Q. Did you do it in the Starbucks, in the parking lot?

A. In the parking lot.

Q. Did you talk first?

A. Yes.

Q. What did you say?

A. I just introduced myself.

Q. Did Mr. Mulleady say anything?

A. Just greetings. He didn't speak a lot.

Q. Did you physically hand the bottles to Mr. Mulleady?

A. Yes.

Q. And it was all five bottles?

A. Yes.

Q. Did Mr. Mulleady give you anything in return to the Starbucks parking lot?

A. Yes.

MS. STEWART: Objection. Leading.

THE COURT: Overruled.

Q. What did Mr. Mulleady give you?

A. He give me an agreement to sign.

Q. Did he say anything?

A. No.

Q. Did you say anything when he handed you the agreement?
A. Yes.
Q. What did you say?
A. I am going to get ready to review it by an attorney and get back to him.
Q. How long did the entire meeting in the Starbucks parking lot take?
A. Less than five minutes.
THE COURT: Are you about to move on? Yes, counsel.
MR. WEINGARTEN: I think I have one more question, if it's a good breaking point.
THE COURT: You're done with the parking lot?
MR. WEINGARTEN: Yes, your Honor.
THE COURT: How did you and Mr. Mulleady find each other in the parking lot?
THE WITNESS: He had exchanged a contact number. I have the telephone number of Kevin Mulleady, and we coordinated.
THE COURT: Thank you.
MR. WEINGARTEN: I'd like to introduce GX-3129. I believe it's already admitted, but if you can please that on the screen, Ms. Guy.
Q. What is this document, sir?
A. I believe this is an agreement, a draft given to me.
Q. Is this the agreement that Mr. Mulleady handed you in the

parking lot?
A. Yes.
Q. Did you ever sign this agreement?
A. No.
MR. WEINGARTEN: You can take that down, Ms. Guy.
Q. Now, let's talk about what happened after you return the bottles.
THE COURT: Excuse me, counsel. We are going to want to take a break at some point here. Is this a good time?
MR. WEINGARTEN: Yes, your Honor.
THE COURT: Thank you. We will have a brief afternoon recess.
(Recess)
THE COURT: Let me just make sure that defense counsel is ready.
MS. STEWART: May I go get the counsel in the hall?
THE COURT: Sure.
Counsel.
BY MR. WEINGARTEN:
Q. Mr. Valiveti, I just want to take you back one second to after the bottles were delivered to CentraState from ASD before you got -- Vyera called CentraState. OK. After the bottles were delivered to CentraState but before the call, what was your intention to do with those bottles?
MS. STEWART: Objection.

THE COURT: Overruled.

A. Supply to get the bottles to Reliant and supply it to the client.

Q. Which client, sir?

A. Dr. Reddy's.

Q. Let's talk about after the Starbucks parking lot meeting. After you met Mr. Mulleady in the parking lot and returned the five bottles, what did you do with DRL's prepayment?

A. We refunded -- we returned the money to DRL.

Q. All of it?

A. All of it.

Q. Did there come a time after that when DRL asked you to again try to procure Daraprim?

A. That's right.

Q. Do you remember when?

A. I think somewhere in 2018.

MR. WEINGARTEN: Ms. Guy, could you please raise up GX-3135, please. It's page 006. I just want to --

Q. Is it possible, sir, that looking at an e-mail that you sent about this topic would refresh your recollection?

A. Yes.

MR. WEINGARTEN: Let's turn to page 006 of Government Exhibit 3135. Could you go to the bottom couple of e-mails there. Thank you very much.

Q. Look at those to yourself, sir. You don't have to say

anything out loud.

Does that refresh your recollection as to the date when DRL approached Reliant again about Daraprim?

A. Yes.

Q. When did DRL again approach Reliant about Daraprim?

A. May 25, 2018.

MR. WEINGARTEN: Thank you. You can take that down, Ms. Guy, please.

Q. How many bottles did Dr. Reddy's ask Reliant to source at that time?

A. Two.

Q. And did it remain as two or did they ask for more?

A. I believe they asked for one more.

Q. How many bottles total, starting in May 2018, did Dr. Reddy's ask Reliant to source?

A. Three bottles.

Q. And did you tell Dr. Reddy's or Cerovene anything about procuring Daraprim at that time?

A. Yes.

Q. What did you tell them?

A. Reliant is going to try from different source.

Q. Did you tell them anything more about why Reliant was going to have to try different sources?

A. I don't recollect.

Q. How much Daraprim from that three-bottle order were you

ultimately able to deliver to DRL?

A. One bottle.

Q. How did you get that one bottle?

A. We got it from a third-party distributor, Bilcare.

Q. That's spelled B-i-l-c-a-r-e?

A. That's right.

Q. What is Bilcare?

A. They are a clinical supplies company. They have -- they also have the same business model as Reliant.

Q. How many bottles did you ask Bilcare to assist you with sourcing?

A. Three bottles.

Q. How many bottles did Bilcare deliver?

A. One bottle.

Q. Did you deliver that bottle to DRL?

A. Yes.

Q. Do you remember when?

A. I don't recollect that.

Q. Did you think it would refresh your recollection if you looked at an invoice that you sent DRL?

A. Yes.

MR. WEINGARTEN: Can you put GX-3039 on the screen. I believe this document is already admitted, your Honor.

Q. What is this document, sir?

A. This is a pro forma invoice.

Q. From whom?
A. From Specialty Pharma Source.
Q. Do you own Specialty Pharma Source?
A. Yes.
Q. Who is it to?
A. To Dr. Reddy's.
Q. Who is it to be shipped to?
A. Cerovene.
Q. What product?
A. Daraprim.
Q. How much?
A. One bottle.
Q. Does that refresh your recollection as to when you may have delivered a bottle of Daraprim to DRL?
A. No. This is a pro forma invoice.
Q. How much did you charge DRL for that one bottle of Daraprim?
A. 110,000.
MR. WEINGARTEN: You can take that down, please, Ms. Guy.
Q. Was that the only bottle you ever were able to procure for Dr. Reddy's?
A. That's right.
Q. Let's turn back quickly to Fera. After you had delivered two bottles to Fera in January of 2018, did Fera ever ask you

to do more?
A. There was an inquiry for additional bottles of Daraprim.
Q. What did you say?
A. I said we can try.
Q. Were you able to procure any more Daraprim for Fera?
A. No. They haven't issued any purchase orders.
Q. Have any other companies approached you after April 2018 about procuring Daraprim?
A. I don't remember.
Q. Is it possible you could refresh your recollection by looking at your deposition, sir?
MR. WEINGARTEN: Ms. Guy, could you please put page 150 of Mr. Valiveti's deposition on the screen, lines 7 through 11.
Q. Read that to yourself, sir. Let me know when you are finished.
A. Yes.
MR. WEINGARTEN: You can take that down, Ms. Guy.
Q. Did that refresh your recollection about whether other companies have asked you to source Daraprim?
A. I think so, but I don't remember that company name.
Q. What was your response to inquiries from any other companies about sourcing Daraprim?
A. We can try.
MR. WEINGARTEN: Ms. Guy, can you please put that back

up, page 150, line 7 to 11.

Q. You testified, sir -- the question was:

"Q. OK. So other companies asked you to provide samples. Sorry. Provide Daraprim products. And you did not respond because of the difficulties you've had in the past acquiring Daraprim.

"A. Correct."

Was that your testimony at your deposition, sir?

A. Yes.

Q. Was that testimony truthful when you gave it?

A. Yes.

Q. So I am going to ask you, sir, why did you not respond to other companies who asked you to help source Daraprim?

A. Usually, like we pick and choose the companies whom we do the business. There may be inquiries and maybe did not respond, if possible, because we had difficulty in sourcing the product.

Q. So did you not respond because you had difficulty sourcing Daraprim?

A. That's right.

MR. WEINGARTEN: I have nothing further at this time.

CROSS-EXAMINATION

BY MS. STEWART:

Q. Good afternoon, I have a few follow-up questions for you.

During the direct examination I believe you spoke

about how sometimes Reliant is unable to source a pharmaceutical product from any source, correct?

A. That's right.

Q. And this is because pharmaceutical manufacturers sometimes place restrictions on who a product can be supplied to, correct?

A. Correct.

Q. For example, I think you testified earlier that manufacturers can restrict the sale of a pharmaceutical product to a class of trade, correct?

A. Correct.

Q. In your experience, pharmaceutical manufacturers have increasingly restricted the sale of their products to specific classes of trade, correct?

A. Correct.

Q. So the practice is becoming more commonplace?

A. All I can say is I can see a trend. I don't know --

Q. You see a trend of more?

A. Yes.

Q. Not including Daraprim, manufacturers have placed restrictions on products that Reliant has tried to source, correct?

A. Correct.

Q. In fact, Reliant Specialty has been unable to source many products due to manufacturer restrictions, correct?

A. Correct.
Q. I believe you testified earlier that it was close to 20 per year. Is that accurate?
A. Yes.
Q. How long has Reliant been in business?
A. Since 2013.
Q. Since 2013, is it fair to say that there has been 20 products or so each year that you have not been able -- that Reliant has not been able to source?
A. About 20 products each year they may have request same products. They keep on trying. All I can say is 20 instance.
Q. I'm sorry. I couldn't quite hear you.
A. Every year like I had 20 inquiries where we can try and get feedback from the manufacturers where we get answer from manufacturer that Reliant is not a class of trade for that particular product.
THE COURT: Counsel, I think, just so you know what I think the witness said and what might be captured here, for some products that you cannot source you get another request for that same product or to source that same product year after year.
THE WITNESS: That's right.
THE COURT: So it may be 20 products in all because the same products get asked for year after year.
THE WITNESS: It's a mixture of new and old product

requests that we keep on trying with manufacturer to see if there are any change in classification by the manufacturer.

THE COURT: If you have 20 such requests a year that you can't fill, how many individual products, say, over last five years have you been unable to fill?

THE WITNESS: More than 20 products all those years.

Q. Are you able to estimate for me how many products since Reliant started business Reliant has been unable to source?

A. I don't have an exact answer, but they are increasingly difficult in sourcing the products.

Q. So you don't remember today how many products Reliant has been able to source?

THE COURT: Has been unable to source.

MS. STEWART: Has been unable. Yes, your Honor.

A. Most of the biologics we have not been able to source.

Q. My question is, as you sit here today, you don't recall how many products you've been unable to source?

A. More than 20, I would say.

Q. Would it help if I showed you your deposition testimony in this case?

A. Yes.

MS. STEWART: Could you bring up the testimony at page 40, please. 41. Apologies.

Q. Do you see on the screen, this is a page from your deposition testimony?

A. Yes.

Q. Do you see the question at the top of the page that begins, I see?

A. Yes.

Q. Can you read this testimony to yourself and your answer and tell me if that helps refresh your recollection?

A. Yes.

Q. Now that your recollection has been refreshed, how many products has Reliant failed to source, approximately?

A. Close to a hundred products.

Q. A hundred products. Thank you.

I believe you also testified earlier that Dr. Reddy's is a large client of Reliant, is that correct?

A. Yes.

Q. And you've been unable to source products separate from Daraprim, there are other products you have been unable to source for Dr. Reddy's, correct?

A. Correct.

Q. You also testified earlier about obtaining Daraprim for a company called Fera, correct?

A. Yes.

Q. And Reliant was able to source two bottles of Daraprim for Fera, correct?

A. Yes.

Q. And it sourced those bottles in January of 2018, is that

correct?
A. Right.
Q. And those bottles were sourced from CentraState, correct?
A. That's correct.
Q. At this time you could have obtained more bottles from CentraState, correct?
A. We ordered five.
Q. I'm talking specifically about the January 28 time frame.
A. Can you repeat the question.
Q. Yes. In January of 2018, Reliant could have ordered more bottles of Daraprim from CentraState, correct?
A. We only have only two bottles ordered.
Q. You only ordered two, but you could have ordered more at that time, correct?
A. We had only request from one client, two bottles.
Q. But nothing was keeping you from ordering more bottles at that time?
A. I don't know.
Q. Would it help if I showed you some of your testimony again.
MS. STEWART: Could I see page 97, please.
Q. Do you see your answer? Does this help refresh your recollection as to whether Reliant could have ordered more Daraprim from CentraState? Does this refresh your recollection as to whether Reliant could have ordered more Daraprim from CentraState?

A. In January 2018.
Q. The January 2018 time frame.
A. Yes.
Q. Thank you.

Now, on direct you were asked a question about whether Fera asked you to order more Daraprim after the two bottles that we were just talking about. I'd like to show you a document with regard to that.

MS. STEWART: Could you bring up DX-121, please.

Q. I am going to ask you to take a look at this document. Is that your e-mail address at the top of the page?
A. Yes.
Q. Do you recognize this document?
A. Yes.
Q. What is this?
A. I sent an e-mail to Fera Pharma to see if they need any additional quantity of Daraprim.
Q. Did Fera respond to you?
A. Yes.
Q. How did they respond?
A. They said they are good for now.
Q. Reliant offered or asked if Fera needed any more Daraprim and Fera declined your offer. Is that fair to say?
A. That's right.

MS. STEWART: Your Honor, I would like to move DX-121

into evidence.

MR. WEINGARTEN: No objection.

THE COURT: Received.

(Defendant's Exhibit 121 received in evidence)

Q. During your direct testimony you were asked about an e-mail you sent to Ms. Kirby, correct?

A. Yes.

Q. That e-mail was sent in the beginning of January 2018, correct?

A. Yes.

Q. But you were able to source Daraprim after you sent that e-mail, correct?

A. We don't source it from retail pharmacies in general.

Q. Let me rephrase my question. I apologize.

After the e-mail to Ms. Kirby, Reliant was able to obtain most two bottles of Daraprim, correct?

A. Yes.

MS. STEWART: No further questions, your Honor.

MR. WEINGARTEN: A very brief redirect, if I may, your Honor.

THE COURT: Yes.

REDIRECT EXAMINATION

BY MR. WEINGARTEN:

Q. You were just asked on cross, sir, about restrictions and trends in restrictions on pharmaceuticals. Do you remember

that?

A. Yes.

Q. Has any manufacturer ever bought back product in a Starbucks parking lot from you other than Vyera?

A. No.

Q. You were asked about two bottles that were delivered to Fera. Do you recall that?

A. Yes.

Q. After you sourced the two bottles in January for Fera, did anyone from Vyera call CentraState?

A. No.

Q. After you sourced five bottles for DRL, did someone from Vyera call CentraState?

A. Yes.

Q. You were shown Defense Exhibit 121 and that was the e-mail where you offered the source and someone from Fera said, we are good for now. Do you remember that?

A. Yes.

Q. Do you remember the date of that e-mail?

MR. WEINGARTEN: Maybe we can put it on the screen, Defense Exhibit 121, please. The top two e-mails, please.

Q. Your e-mail is dated February 12, 2018, right?

A. That's right.

Q. That's to people at Fera?

A. Yes.

Q. Is February 12, 2018 before or after the phone call from Vyera to CentraState?

A. This is before our call from Vyera.

Q. Is February 12, 2018 before or after you met Mr. Mulleady in the Starbucks parking lot?

A. After.

Q. Before or after?

A. After February 12.

Q. You met Mr. Mulleady in the Starbucks parking lot after February 12?

A. Yes.

MR. WEINGARTEN: Nothing further.

THE COURT: Any recross?

MS. STEWART: No, your Honor.

THE COURT: Sir, you may step down.

THE WITNESS: Thank you.

(Witness excused)

THE COURT: Next.

(Continued on next page)

MR. MEIER: Your Honor, as I mentioned before the lunch break, we're out of witnesses for today, and I apologize to the Court, but we did as much as we could, and this is the best we could do.

THE COURT: Great. So give me just a second here.

I'll confirm, but I think the plaintiffs have used nine hours and fifty-eight minutes and the defendant has used ten hours and twenty-five minutes. We have a little less than one hour of the trial day remaining.

So let me see. Somehow I'm subtracting the one hour from the allocations but I'll let counsel reflect on how that should be allocated. And it may be irrelevant — you may not need all your time, and that's just fine — I'm sure you'll have additional time to prepare for your summations.

It would be fine with me if you started your summations before Wednesday, but we had set aside Wednesday for summations, not that they will take the whole day, but is that still counsel's preferred schedule?

MR. MEIER: Speaking on behalf of the government, Markus Meier again, yes, your Honor, it would be our preference, regardless of what time we finish on Tuesday, to just start summation on 9:30 on Wednesday.

THE COURT: Perfect. That's the schedule that we will follow.

I take it that's agreeable to the defendant, as well,

and, indeed, your preference?

MR. CASEY: Yes, it is, your Honor.

THE COURT: Okay, good.

So it's fine with me if we end early on Tuesday and that will give you even more time to make your final preparations for summation.

I'll let you go. I hope you have a good weekend, everyone stays healthy, and I don't know if there are any issue that you need to address with me. I'm unaware of anything.

So good have a good weekend.

(Adjourned to December 20, 2021 at 9:30 a.m.)

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